



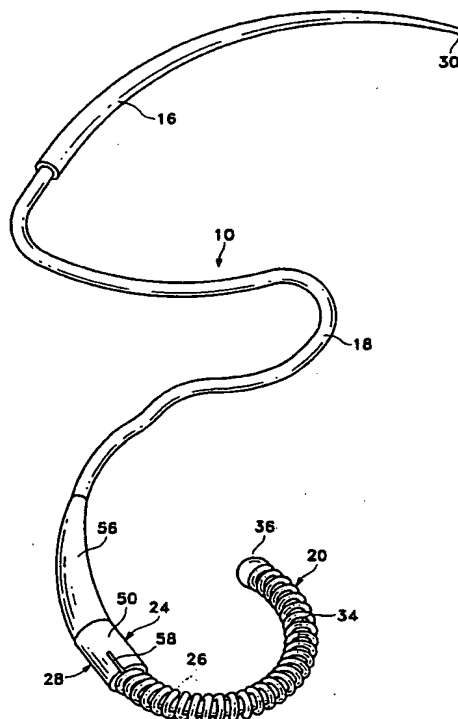
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(71) Applicant (for all designated States except US): COALES-CENT SURGICAL, INC. [US/US]; 559 East Weddell Drive, Sunnyvale, CA 94089 (US).			
(72) Inventors; and (75) Inventors/Applicants (for US only): SCHALLER, Laurent [CH/US]; 595 Benvenue Avenue, Los Altos, CA 94024 (US). GARDINER, Barry [US/US]; 13 Charles Hill Road, Orinda, CA 94563 (US). GANDIONCO, Isidro, Matias [US/US]; 36520 Alder Court, Fremont, CA 94536 (US). NGUYEN, John [US/US]; 4053 Forestwood Drive, San Jose, CA 95121 (US). HILL, Art [US/US]; 2000 Broadway #512, San Francisco, CA 94115 (US). HO, Liem [VN/US]; 2235 California Street #158, Mountain View, CA 94040 (US).			
(74) Agents: MACEY, Harry, J. et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).			

(54) Title: TISSUE CONNECTOR APPARATUS AND METHODS

(57) Abstract

A tissue connector assembly having a flexible member and a surgical fastener such as a surgical clip releaseably coupled to the flexible member. A needle may be secured to one end portion of the flexible member with the surgical clip coupled to the other end portion of the flexible member. A locking device may be used to releaseably couple the flexible member to the surgical clip. The tissue connector assembly may have one or more piercing members, each releaseably coupled to the surgical fastener. A flexible member such as a suture may be used to couple one or both piercing members to respective ends of the fastener.



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INTERNATIONAL SEARCH REPORT

Inter. Appl. No.

PCT/US 99/12566

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61B17/064 A61B17/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 242 456 A (NASH) 7 September 1993 (1993-09-07)	1
A	figures 15,24 ---	25,79
X	EP 0 641 546 A (ETHICON) 8 March 1995 (1995-03-08)	1
	figure 18 ---	
X	US 5 374 268 A (SANDER) 20 December 1994 (1994-12-20)	44,50, 52,53
A	column 3, last paragraph; figures 1,2,4,6 ---	54
X	WO 97 32526 A (YOON) 12 September 1997 (1997-09-12)	1,7,9, 10,12, 13,15,16
A	figures 4A,16,25,35 ---	51,71
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search

26 January 2000

Date of mailing of the international search report

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European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651.epo.nl,
 Fax: (+31-70) 340-3016

Authorized officer

Barton, S

INTERNATIONAL SEARCH REPORT

Inter. Patent Application No

PCT/US 99/12566

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 002 563 A (PYKA) 26 March 1991 (1991-03-26) column 5, line 10 - line 12; figures 4,5 ---	1,25,79
A	US 3 958 576 A (KOMIYA) 25 May 1976 (1976-05-25) figure 1 ---	1,25,79
A	US 5 609 608 A (UNIV CALIFORNIA) 11 March 1997 (1997-03-11) figure 6 ---	23
A	DE 195 47 617 C (NEUS MALTE) 18 September 1997 (1997-09-18) figures 4,9 ---	23
A	US 4 586 502 A (BEDI) 6 May 1986 (1986-05-06) ---	
A	DE 219 999 C (KRATZ) figure ---	
A	US 3 249 104 A (HOHNSTEIN) 3 May 1966 (1966-05-03) -----	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/12566

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 30-40, 119-125
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
1-29, 44-112
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-22,25-29,79-112

Tissue connector assembly with releasably coupled needle/suture combination and surgical clip

2. Claims: 23,24

Needle/suture combination with locking device

3. Claims: 44-78

Surgical fastener with double piercing member

4. Claims: 113-115

Connection means using compressed tube

5. Claim : 116

Connection means with interlocking grooves and projections

6. Claim : 117

Connection means with knot/constriction

7. Claim : 118

Connector with integral severing means

8. Claims: 126,127

Hollow suture

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/12566

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US99/12566 (22) International Filing Date: 3 June 1999 (03.06.99) (30) Priority Data: 09/089,884 3 June 1998 (03.06.98) US 09/260,623 1 March 1999 (01.03.99) US (71) Applicant (for all designated States except US): COALES- CENT SURGICAL, INC. [US/US]; 559 East Weddell Drive, Sunnyvale, CA 94089 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): SCHALLER, Laurent [CH/US]; 595 Benvenue Avenue, Los Altos, CA 94024 (US). GARDINER, Barry [US/US]; 13 Charles Hill Road, Orinda, CA 94563 (US). GANDIONCO, Isidro, Matias [US/US]; 36520 Alder Court, Fremont, CA 94536 (US). NGUYEN, John [US/US]; 4053 Forestwood Drive, San Jose, CA 95121 (US). HILL, Art [US/US]; 2000 Broadway #512, San Francisco, CA 94115 (US). HO, Liem [VN/US]; 2235 California Street #158, Mountain View, CA 94040 (US). (74) Agents: MACEY, Harry, J. et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: TISSUE CONNECTOR APPARATUS AND METHODS (57) Abstract A tissue connector assembly having a flexible member and a surgical fastener such as a surgical clip releaseably coupled to the flexible member. A needle may be secured to one end portion of the flexible member with the surgical clip coupled to the other end portion of the flexible member. A locking device may be used to releaseably couple the flexible member to the surgical clip. The tissue connector assembly may have one or more piercing members, each releaseably coupled to the surgical fastener. A flexible member such as a suture may be used to couple one or both piercing members to respective ends of the fastener.		

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TISSUE CONNECTOR APPARATUS AND METHODS

FIELD OF THE INVENTION

The present invention relates to instruments and methods for connecting body tissues, tissue and prostheses, tissue and graft or any combination thereof.

5

BACKGROUND OF THE INVENTION

Minimally invasive surgery has allowed physicians to carry out many surgical procedures with less pain and disability than conventional, open surgery. In performing minimally invasive surgery, the surgeon may make a number of small incisions through the body wall to obtain access to the tissues requiring treatment. Typically, a trocar, which is a pointed, piercing device, is delivered into the body with a cannula. After the trocar pierces the abdominal or thoracic wall, it is removed and the cannula is left with one end in the body cavity, where the operation is to take place, and the other end opening to the outside. A cannula may have a small inside diameter, typically 5-10 millimeters, and sometimes up to as much as 20 millimeters. A number of such cannulas are inserted for any given operation.

A viewing instrument, typically including a miniature video camera or optical telescope, may be inserted through one of these cannulas and a variety of surgical instruments and refractors inserted through others. The image provided by the viewing device may be displayed on a video screen or television monitor, affording the surgeon enhanced visual control over the instruments. Because a commonly used viewing instrument is called an "endoscope," this type of surgery is often referred to as "endoscopic surgery." In the abdomen, endoscopic procedures are commonly referred to as laparoscopic surgery, and in the chest, as thoracoscopic surgery. Abdominal procedures may take place either inside the abdominal cavity (in the intraperitoneal space) or in a space created behind the abdominal cavity (in the retroperitoneal space). The retroperitoneal space is particularly useful for operations on the aorta and spine, or abdominal wall hernia.

Minimally invasive surgery has been used in place of open surgical techniques for operations such as cholecystectomy and anti-reflux surgery of the esophagus and stomach.

This has not occurred in either peripheral vascular surgery or cardiovascular surgery. An important type of vascular surgery is to replace or bypass a diseased, occluded or injured artery. Arterial replacement or bypass grafting has been performed for many years using open surgical techniques and a variety of prosthetic grafts. These grafts are manufactured as fabrics (often from DACRON® (polyester fibers) or TEFLON® (fluorocarbon fibers)) or are prepared as autografts (from the patient's own tissues) or heterografts (from the tissues of animals) or a combination of tissues, semi-synthetic tissues and or alloplastic materials. A graft can be joined to the involved artery in a number of different positions, including end-to-end, end-to-side, and side-to-side. This attachment between artery and graft is known as an anastomosis. Constructing an arterial anastomosis is technically challenging for a surgeon in open surgical procedures, and is almost a technical impossibility using endoscopic minimally invasive techniques.

Many factors contribute to the difficulty of performing arterial replacement or bypass grafting. See generally, Wylie, Edwin J. et al., Manual of Vascular Surgery, (Springer-Verlag New York), 1980. One such factor is that the tissues to be joined must be precisely aligned with respect to each other to ensure the integrity and patency of the anastomosis. If one of the tissues is affixed too close to its edge, the suture can rip through the tissue and impair both the tissue and the anastomosis. Another factor is that, even after the tissues are properly aligned, it is difficult and time consuming to pass the needle through the tissues, form the knot in the suture material, and ensure that the suture material does not become tangled. These difficulties are exacerbated by the small size of the artery and graft. The arteries subject to peripheral vascular and cardiovascular surgery typically range in diameter from several millimeters to several centimeters. A graft is typically about the same size as the artery to which it is being attached. Another factor contributing to the difficulty of such procedures is the limited time available to complete the procedure. The time the surgeon has to complete an arterial replacement or bypass graft is limited because there is no blood flowing through the artery while the procedure is being done. If blood flow is not promptly restored, sometimes in as little as thirty minutes, the tissue the artery supplies may experience significant damage, or even death (tissue necrosis). In addition, arterial replacement or bypass grafting is made more difficult by the need to accurately place and space many sutures to achieve a permanent hemostatic seal. Precise

placement and spacing of sutures is also required to achieve an anastomosis with long-term patency.

Highly trained and experienced surgeons are able to perform arterial replacement and bypass grafting in open surgery using conventional sutures and suturing techniques. A suture needle is attached or "swedged on" to a long, trailing suture material. The needle must be precisely controlled and accurately placed through both the graft and artery. The trailing suture material must be held with proper tension to keep the graft and artery together, and must be carefully manipulated to prevent the suture material from tangling. In open surgery, these maneuvers can usually be accomplished within the necessary time frame, thus possibly avoiding the subsequent tissue damage (or tissue death) that can result from prolonged occlusion of arterial blood flow.

A parachuting technique may be used to align the graft with the artery in an end-to-side anastomosis procedure. With this technique, one or multiple sutures are attached to the graft and artery and are used to pull or "parachute" the graft vessel into alignment with an opening formed in a sidewall of the artery. The graft vessel and artery opening edges may be everted as is known in the art. Among the drawbacks to this procedure are the difficulty in preventing the suture from tangling and the time and surgical skill required to tie individual knots when using multiple sutures. Due to space requirements, this procedure is generally limited to open surgery techniques.

The difficulty of suturing a graft to an artery using minimally invasive surgical techniques has effectively prevented the safe use of this technology, in both peripheral vascular and cardiovascular surgical procedures. When a minimally invasive procedure is done in the abdominal cavity, the retroperitoneal space, or chest, the space in which the operation is performed is more limited, and the exposure to the involved organs is more restricted, than with open surgery. Moreover, in a minimally invasive procedure, the instruments used to assist with the operation are passed into the surgical field through cannulas. When manipulating instruments through cannulas, it is extremely difficult to position tissues in their proper alignment with respect to each other, pass a needle through the tissues, form a knot in the suture material once the tissues are aligned, and prevent the suture material from becoming tangled. Therefore, although there have been isolated reports of vascular anastomoses being formed by minimally invasive surgery, no system

has been provided for wide-spread surgical use which would allow such procedures to be performed safely within the prescribed time limits.

As explained above, anastomoses are commonly formed in open surgery by suturing together the tissues to be joined. However, one known system for applying a clip around tissues to be joined in an anastomosis is disclosed in a brochure entitled, "VCS Clip
5 Applier System", published in 1995 by Auto Suture Company, a Division of U.S. Surgical Corporation. A clip is applied by applying an instrument about the tissue in a nonpenetrating manner, i.e., the clip does not penetrate through the tissues, but rather is clamped down around the tissues. As previously explained, it is imperative in forming an
10 anastomosis that tissues to be joined are properly aligned with respect to each other. The disclosed VCS clip applier has no means for positioning tissues. Before the clip can be applied, the tissues must first be properly positioned with respect to each other, for example by skewering the tissues with a needle as discussed above in common suturing techniques or with forceps to bring the tissues together. It is extremely difficult to perform such
15 positioning techniques in minimally invasive procedures.

Therefore, there is currently a need for other tissue connecting systems.

SUMMARY OF THE INVENTION

The present invention involves apparatus and methods for connecting material, at
20 least one of which is tissue. The invention may, for example, be used to secure one vessel to another, such as in a vascular anastomosis.

According to one aspect of the invention, a tissue connector assembly is provided and comprises a flexible member and a surgical clip which may be releasably coupled to the flexible member. With this construction, a needle may be coupled to the flexible
25 member, which may be in the form of a suture, to facilitate, for example, parachuting suture tissue connecting procedures. The surgical clip may eliminate the need for tying sutures, which requires significant skill, space, and time.

According to another aspect of the invention a tissue connector assembly comprises a needle, a flexible member coupled to the needle, and a locking device coupled to the
30 flexible member. The locking device is adapted for receiving a surgical fastener. Thus, a surgical fastener may be selected based on a desired procedure and coupled to the locking

device to facilitate, for example, parachuting suture tissue connecting procedures as discussed above.

According to another aspect of the invention, a method for connecting tissues includes drawing portions of tissue together with a clip assembly and securing the tissue portions together with the clip assembly.

According to another aspect of the invention, multiple portions of material are drawn together with a tissue connector assembly having a clip in an open position. At least one of the portions of material is tissue. The clip is closed to secure the material portions therein. The materials may be drawn together by pulling the tissue connector assembly with at least a portion of the clip positioned in the materials. A needle may be used to insert the tissue connector assembly into the material. A portion of the tissue connector assembly may be manipulated to simultaneously actuate closure of the clip and release the needle from the clip.

According to another aspect of the invention, a tissue connector assembly is inserted through graft and target vessels with the graft vessel being spaced from the target vessel. The tissue connector assembly has a first end extending from an exterior surface of the graft vessel and a second end extending from an exterior surface of the target vessel. At least one end of the tissue connector assembly is pulled to draw the graft vessel into contact with the target vessel.

According to another aspect of the invention, a tissue connector assembly is inserted through the graft and target vessels with the graft vessel being spaced from the target vessel and the tissue connector assembly having a first end extending from an exterior surface of the graft vessel and a second end extending from an exterior surface of the target vessel. At least a portion of the tissue connector assembly is pulled to draw the graft vessel into contact with the target vessel.

According to another aspect of the invention a tissue connecting assembly may include multiple piercing members coupled to a surgical fastener. According to one embodiment, a tissue connector assembly is provided comprising a surgical fastener, such as a surgical clip, a first tissue piercing member and a second tissue piercing member. The fastener may be adapted to assume a loop configuration. The fastener has a first end portion and a second end portion. The first tissue piercing member is coupled to the first

end portion and the second tissue piercing member is coupled to the second end portion. The multiple piercing member construction facilitates threading ends of the assembly from inner to outer walls of material, such as tissue, which may eliminate or minimize the possibility of dislodging material from the inner wall of a vessel, for example.

5 According to another aspect of the invention, a flexible member, such as a suture, may be provided between at least one piercing member and the fastener to facilitate threading the fastener and/or "parachute" techniques, for example.

 According to another aspect of the invention, synchronized piercing member release mechanisms may be provided. In one embodiment, the tissue connector assembly may
10 include a first coupling, which couples the first tissue piercing member and first end portion of the surgical fastener, and a second coupling, which couples the surgical fastener second end portion and second piercing member. The first coupling releases the other coupling in response to releasing the first coupling. According to one aspect of this embodiment, multiple tissue piercing members may be decoupled from the surgical
15 fastener with one release actuator. According to another aspect, the piercing members may be decoupled essentially simultaneously.

 The above is a brief description of some deficiencies in the prior art and advantages of the present invention. Other features, advantages, and embodiments of the invention will be apparent to those skilled in the art from the following description, accompanying
20 drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

 Fig. 1 is a perspective view of a tissue connector assembly of the present invention;
25 Fig. 1A is a partial sectional view illustrating an alternate construction of flexible member 18 of Fig. 1;

 Fig. 1B is a partial sectional view illustrating yet another construction of flexible member 18 of Fig. 1;

 Figs. 2A-2E diagrammatically illustrate a method of aligning and connecting graft and target vessels with the single piercing member tissue connector assembly of Fig. 1,
30 where Fig. 2A shows two tissue connector assemblies threaded through a graft and target

vessel, Fig. 2B shows a further step in connecting the graft and target vessel, Fig. 2C shows a further step for connecting the graft and target vessel with the fastener positioned in the graft and target vessels, Fig. 2D shows the graft vessel connected to the target vessel, and Fig. 2E shows a front view of the connected graft and target vessels of Fig. 2D, with portions broken away to show detail;

Fig. 2F is an enlarged view of the tissue connection shown in Fig. 2E;

Fig. 2G shows an alternate method for connecting the graft vessel to the target vessel with the tissue connector assembly of Fig. 1;

Figs. 3A, 3B and 3C show a fastener which can be used with the tissue connector assembly of Figs. 1, 9, 10 or 17, for example, where Fig. 3A is a top view of the fastener in a closed position, Fig. 3B is a side view of the fastener of Fig. 3A, and Fig. 3C is an enlarged view of the fastener of Fig. 3A in an open position;

Fig. 4 is a top view of another fastener configuration, which can be used with the tissue connector assembly of Fig. 1, 9, 10 or 17, for example;

Figs. 5A and 5B show yet another fastener configuration which can be used with the tissue connector assembly of Figs. 1, 9, 10 or 17, for example, where Fig. 5A shows the fastener in a closed position and Fig. 5B is a side view of the fastener of Fig. 5A;

Fig. 6A-6F show further fastener configurations which can be used with the tissue connector assembly of Figs. 1, 9, 10 or 17, for example where Fig. 6A is a top view of a fastener in a closed position, Figs. 6B, 6C and 6D are top views of variants of that shown in Fig. 6A, Fig. 6E is a side view of Fig. 6D taken along line 6E--6E of Fig. 6D, and Fig. 6F is an example of a graft to thick tissue anastomosis using the fastener shown in Fig. 6D;

Figs. 7A, 7B and 7C illustrate a release mechanism which can be used with any of the fasteners described above and the tissue connector assembly of Figs. 1, 9, 10 or 17, for example, where Fig 7A shows the restraining device in cross-section and in a locked position, Fig. 7B is a transverse cross-sectional view of the restraining device taken in a plane along line 7B--7B of Fig. 7A, and Fig. 7C is a cross-sectional view of the restraining device of Fig. 7A in an unlocked position;

Fig. 8 is an alternate embodiment of a restraining device;

Fig. 9 is a front view of another embodiment of a single piercing member tissue connector assembly according to the present invention and shown in an open position.

Fig. 10 is a perspective view of a tissue connector assembly constructed in accordance with the principles of the present invention;

Figs. 11A, 11B and 11C illustrate another release mechanism which can be used with any of the fasteners or tissue connector assemblies described above, where Fig 11A shows the restraining device in cross-section and in a locked position, Fig. 11B is a transverse cross-sectional view of the restraining device taken in a plane along line 11B--11B of Fig. 11A, and Fig. 11C is a cross-sectional view of the restraining device of Fig. 11A in an unlocked position;

Figs. 12A-12E illustrates yet another release mechanism which can be used with any of the fasteners described above, where Fig. 12A shows a perspective view of the retaining device coupled with a fastener, Fig. 12B is a sectional view of the retaining device of Fig. 12A, Fig. 12C is a transverse cross-sectional view of the restraining device taken along line 12C-12C in Fig. 12B, Figs. 12D and 12E are perspective and end views of the restraining device, respectively, showing the device depressed for release of the fastener; and Fig. 12F shows the retaining device of Fig. 12A with an adapter for coupling to the other end of the fastener;

Figs. 13A-13C show a synchronized fastener release system, where Figs. 13A and 13C are partial sectional views of the system in a coupled and decoupled state, respectfully, and Fig. 13B is a sectional view taken along lines 13B-13B in Fig. 13A;

Figs. 13D-13F show another synchronized fastener release system where Figs. 13D and 13E are partial sectional views of the system in a coupled and decoupled state, respectfully, and Fig. 13F is a transverse cross-sectional view taken along line 13F-13F in Fig. 13E;

Figs. 14A and 14B are partial sectional views of another release mechanism in a coupled and decoupled state, respectfully;

Figs. 15A and 15B are partial sectional views of a further release mechanism in a coupled and decoupled state, respectfully;

Figs. 16A and 16B are partial sectional views of yet another release mechanism in a coupled and decoupled state, respectfully;

Fig. 17A is a front view of a another embodiment of a tissue connector assembly of the present invention;

Fig. 17B is a sectional view of a piercing member and release mechanism combination, which can be used in the embodiment, illustrated in Fig. 17A;

Figs. 18A-18D diagrammatically illustrate a method of aligning and connecting graft and target vessels with the multiple piercing member tissue connector assembly of Fig. 10, where Fig. 18A shows two such tissue connector assemblies threaded through a graft and target vessel, Fig. 18B shows a further step in connecting the graft and target vessel with the tissue connector assembly fastener is positioned in the target vessel, Fig. 18C shows yet a further step where the graft has been brought into position over the opening formed in the target vessel and the tissue connector assembly fastener positioned through the walls of the graft and target vessel and Fig. 18D shows the fasteners released from the tissue connector assembly of Fig. 10 and securing the graft and target vessel together with additional laterally disposed fasteners; and

Fig. 18E is a partial sectional view of the graft and target vessels with the tissue connector assembly fasteners of Fig. 1 in place prior to placement of additional lateral fasteners.

Corresponding reference characters indicate corresponding elements throughout the drawings.

DESCRIPTION OF THE INVENTION

The present invention generally involves methods and devices for manipulating, aligning and/or connecting tissues, tissue and prosthesis, tissue and graft, or any combination thereof. As used herein, the term graft includes any of the following: homografts, autologous grafts, xenografts, allografts, alloplastic materials, and combinations of the foregoing. Tissue connector assemblies are disclosed, which, for example, may be used in vascular surgery to replace or bypass a diseased, occluded, or injured artery by connecting a graft vessel to a coronary artery or vein in an anastomosis as shown in Figs. 2A-2G or 18A-E. Assemblies constructed in accordance with the invention may be used in open surgical procedures or in minimally invasive or endoscopic procedures for attaching tissue located in the chest, abdominal cavity, or retroperitoneal space. It should be understood, however, that these examples are provided for illustration and are not intended to limit the scope of the invention.

Single or multiple piercing member embodiments are described herein. According to one aspect of the single member embodiment, a piercing member, which may comprise a needle, is releaseably coupled to a fastener. The piercing member may be attached to a flexible member, such as a suture, which in turn is releaseably coupled to the fastener. The coupling between the flexible member (and, thus, the piercing member) and the fastener may be constructed to actuate closure of the fastener upon release of the flexible member (or piercing member). For example, the coupling may hold a compression spring (which is positioned around a fastener) in a compressed state to brace the fastener open and releaseably lock or secure the fastener to the flexible member (or piercing member).

Referring now to the drawings, and first to Fig. 1, a tissue connector assembly constructed according to the principles of the present invention is shown and generally indicated with reference numeral 10. The tissue connector assembly 10 may be used to manipulate and align tissues, or tissue and prosthesis with respect to each other and thereafter connect the tissues or tissue and prosthesis together (Figs. 2A-2G).

In the embodiment shown in Fig. 1, the tissue connector assembly 10 generally comprises a tissue piercing or penetrating member 16, a flexible member 18, and a fastener or surgical clip 20. A restraining device, generally indicated at 24 and comprising a spring (or coil) 26 and a locking device (or coupling member) generally indicated at 28, is connected to the fastener 20 for holding the fastener in a deformed configuration as further described below. Although a particular fastener and accompanying restraining device is shown in Fig. 1, it should be understood that any suitable fastener can be used therein or any of the tissue connector assemblies described herein, including but not limited to the alternate fastener configurations described below. For example, the fastener may be a plastically deformable clip or may comprise two or more parts, at least one of which is movable relative to the other part, such as with a hinged clip. Further, other piercing member release mechanisms can be used with or without restraining devices depending on the fastener construction.

Piercing or penetrating member 16, which may be in the form of a needle (such as a 7-0 or 8-0 needle), has a sharp pointed tip 30 at its distal end for penetrating tissue.

Member 16 may be bent as shown in Fig. 1, for example. The diameter of at least a portion of member or needle 16 is preferably greater than the diameter of flexible member 18 so

that the flexible member can easily be pulled through an opening formed in the tissue by the needle. The distal end of member or needle 16 is preferably rigid to facilitate penetration of tissue. The remaining length of member or needle 16 may be rigid or flexible to facilitate movement of the needle through the tissue as further described below.

5 The tip 30 of member or needle 16 may have various configurations and may, for example, be conical, tapered, or grounded to attain a three or four facet tip. Member or needle 16 may be made from stainless steel or any other suitable material, such as a polymeric material. It is to be understood that member or needle 16 may have a shape or radius of curvature other than the one shown, without departing from the scope of the invention.

10 Member or needle 16 may also be integrally formed with the flexible member 18 (e.g., both needle and flexible member formed of the same material.)

Flexible member 18 may be in the form of a suture formed from conventional filament material, metal alloy such as nitinol, polymeric material, or any other suitable material. The material may be non-stretchable or stretchable, solid or hollow, and have
15 various cross-sectional diameters. The flexible member or suture may have a cross-sectional diameter of .003 inch, for example. The diameter and length of the suture will vary depending on the specific application. The suture may be attached to the needle 16 by crimping or swaging the piercing member or needle onto the suture, gluing the suture to the piercing member or needle, or any other suitable attachment method. Flexible member 18
20 may have cross-sectional shapes other than the one shown herein and may have other constructions as well.

Referring to Fig. 1A, an alternate flexible member construction is shown. Flexible member 18¹ generally comprises a flexible filament 14, which may be in the form of a metal wire, and tube or sleeve 15, which may be in the form of a hollow suture. Tube 15
25 surrounds filament 14 with one end of the filament 14 secured to piercing member 16 and its other end secured to coupling 28 with glue, for example. The filament may provide kink resistance and pull strength (to minimize or eliminate stretch), and is especially advantageous when using very thin material for tube 15. Tube 15 may, for example, comprise polymeric materials such as polyurethane or polyester. It is noted that at least
30 the portions of the tube adjacent to needle 16 and coupling 28 have the same diameter as the portions of the coupling and needle adjacent thereto. This eliminates the need for the

tapered portions 5 and 6 shown in Fig. 1 (portion 2 and 3 of Fig. 10) other transition sections to minimize or eliminate the step between the flexible member and needle and/or the flexible member and the coupling. Of course, the diameter of the entire flexible member may be the same as that of the coupling and the portion of the needle adjacent to the flexible member as indicated in Fig. 1A.

Referring to Fig. 1B, another hollow flexible member construction is shown. Flexible member 18¹¹ comprises tube or sleeve 15, which may be in the form of a hollow suture. Tube 15 is secured to piercing member or needle 16 and coupling 28 through posts or anchors 4, which in turn, are secured to piercing member or needle 16 and coupling 28. The relative dimensions of tube 15 as compared to needle 16 and coupling 28 may be the same as those describe in connection with Fig. 1A for the same reasons.

Referring to Figs. 3-6, one embodiment of a fastener (e.g., fastener 20) comprises a deformable wire 34 made of a shape memory alloy. A nickel titanium (nitinol) based alloy may be used, for example. The nitinol may include additional elements which affect the yield strength of the material or the temperature at which particular pseudoelastic or shape transformation characteristics occur. The transformation temperature may be defined as the temperature at which a shape memory alloy finishes transforming from martensite to austenite upon heating (i.e., A_f temperature). The shape memory alloy preferably exhibits pseudoelastic (superelastic) behavior when deformed at a temperature slightly above its transformation temperature. At least a portion of the shape memory alloy is converted from its austenitic phase to its martensitic phase when the wire is in its deformed configuration. As the stress is removed, the material undergoes a martensitic to austenitic conversion and springs back to its original undeformed configuration. When the wire is positioned within the tissue in its undeformed configuration, a residual stress is present to maintain the tissue tightly together (See e.g., Figs. 2F). In order for the pseudoelastic wire to retain sufficient compression force in its undeformed configuration, the wire should not be stressed past its yield point in its deformed configuration to allow complete recovery of the wire to its undeformed configuration. The shape memory alloy is preferably selected with a transformation temperature suitable for use with a stopped heart condition where cold cardioplegia has been injected for temporary paralysis of the heart tissue (e.g., temperatures as low as 8-10 degrees Celsius).

It is to be understood that the shape memory alloy may also be heat activated, or a combination of heat activation and pseudoelastic properties may be used, as is well known by those skilled in the art.

The cross-sectional diameter of the wire and length of the wire will vary depending on the specific application. The diameter "d" of wire 34 may be, for example, between 0.001 and 0.015 inch. For coronary bypass applications, the diameter is preferably between 0.001 and 0.008 inch with a diameter D of the loop (Fig. 3A) being between 0.0125 and 0.0875 inch. As shown in Fig. 3A and 3B, the wire 34 has a circular cross-sectional shape and a generally ring or loop shaped configuration when in a closed position. The diameter D of the loop of the fastener 20 (with coil 26, which may be platinum) in its closed position is preferably sized to prevent movement between adjacent tissues. It is to be understood, however, that the wire may have other cross-sectional shapes such as rectangular, or may be formed from multiple strands without departing from the scope of the invention.

One end of wire 34, which may be referred to as the proximal end of wire 34, may include an enlarged portion 36 having a cross-sectional area greater than the cross-sectional area of the wire and diameter of the coil to resist the coil from passing thereover. Alternatively, enlarged portion 36 may have a cross-section that allows the coil to be pulled over the enlarged portion. For example, the cross sectional diameter of the enlarged portion may be about equal to the coil diameter. The enlarged portion 36 also may be provided to cooperate with a release mechanism as will be discussed in more detail below. Enlarged portion 36 may be formed by attaching a member to the end of wire 34 by welding, gluing or other suitable attachment means or may be formed integrally with the wire by deforming the end of the wire. The other end of wire 34, which may be referred to as the distal end of wire 34, also may include an enlarged portion 38 for engagement with a restraining device, such as restraining device 24 (see. e.g., Fig. 1), or a locking device or release mechanism, such as release mechanism 28 (see e.g., Fig. 1), as further described below. The enlarged portion 38 may be formed by deforming the end of wire 34 by swaging or arc welding, or attaching an enlarged portion to the end of the wire by welding, swaging, or other suitable means. Although enlarged portions 36 and 38 are shown with spherical and cylindrical configurations, other configurations or configuration

combinations can be used. For example, both enlarged portions may be spherical or cylindrical, or portion 36 may be cylindrical and portion 38 spherical.

Referring to Figs. 3A-C, fastener 20 is shown in open and closed configurations. When wire 34 is in an undeformed or closed configuration (position or state), the fastener is closed (as shown in Figs. 3A and 3B) for keeping or connecting tissue together, and when wire 34 is in a deformed or open configuration (position or state), the fastener is open (as shown in Fig. 3C) for insertion of the wire into tissue. As discussed above, wire 34 is in its closed configuration when in a relaxed state. Wire 34 is preferably not deformed past its yield point in its open position. Accordingly, it may have a U-shaped configuration in its open position to facilitate insertion of the wire through the tissue. It is to be understood that U-shaped configuration may be alternatively substituted by an equivalent structure or configurations such as C-shaped, V-shaped, J-shaped, and other similarly shaped configurations. Wire 34 is moved from its closed position to its open position by a restraining device, as further described below. When in its closed position, wire 34 forms a loop with the ends of the wire in a generally side-by-side or overlapping orientation (Fig. 3B).

Wire 34 may be formed in the above described shape by first wrapping the wire onto a mandrel and heat treating the wire at approximately 400-500 degrees Celsius for approximately 5 to 30 minutes. Wire 34 is then air quenched at room temperature. The mandrel may have a constant diameter or may be conical in shape.

Referring to Fig. 4, an alternate configuration of fastener 20 in its closed position is shown, and generally indicated with reference numeral 40. Fastener 40 forms a spiral configuration in its closed position for trapping the tissue within a loop formed by the spiral. In its open position, the fastener 40 is configured to form less than a full 360 degree turn, and may be made to have an open position as shown in Fig. 3C, for example.

Referring to Figs. 5A and 5B, another configuration of fastener 20 is shown in its closed position, and is generally designated with reference numeral 41. Fastener 41 is formed in a spiral about a central longitudinal axis A. As shown in Fig. 5B, fastener 41 has a generally conical shape along the longitudinal axis A, with a decreasing diameter as the radius of curvature of fastener 41 decreases. Fastener 41 has an inner end portion 45 and an outer end portion 47, with the enlarged portion 38 of the wire being disposed at the outer

end portion for engagement with the restraining device 24 as shown, for example, in Fig. 3C.

Referring to Fig. 6A, a modification of fastener 41 is shown, and generally indicated with reference numeral 43. Fastener 43 is similar to fastener 41 described above, except that enlarged portion 38, which is adapted for engaging a restraining device or releasable locking mechanism, is positioned at the inner end portion 45 of the fastener. Placement of restraining device 24 at the inner end portion 45 of fastener 43 may increase the compression force of the wire in its undeformed position on the tissue and decreases the surface area of the fastener exposed to blood flow. Additionally, one or both ends of the fastener may extend in a substantially straight direction from the curved form of the wire 34, as shown in Figs. 6B-6F. These fasteners are the same as that shown in Fig. 6A with the exception of an added straight section 38' (Fig. 6B), additional straight sections 36' and 38' and a stop "S" (Fig. 6C) and two additional straight sections 36' and 38', a stop and a further quarter turn (Figs. 6D and 6E). The configurations shown in the order of Fig. 6A-6E accommodate fasteners of increasing size. The extensions 36' and 38' preferably extend for a length equal to about two to three times the outside diameter of the coil 26 (as compared to the diameter of the loop) or about 0.010 to 0.020 inches. These extensions may allow the release mechanisms to operate more efficiently and also may simplify manufacture of the fastener.

It is noted that one extension 36' or 38' for use with single needle embodiment such as shown in Figs. 1 or 9, for example. However, the single needle embodiments are not limited to only one extension, and may employ a two extension fastener configuration as well.

The fasteners shown in Figs. 6A or 6B may be embodied by an 8-0 clip size (wire 34), having a cross-sectional thickness of about 0.035 inches, which, in the closed configuration shown, forms an inner loop having a diameter D_1 of about 0.017 inches and an outer loop dimension D_2 horizontally measured from inside of the loop) of about 0.021 inches. In the open configuration the clip forms a U-shape with a depth of the U-shape being about 0.032 inch (0.8mm).

Figs. 6C, 6D and 6E show configurations with two extensions 36' and 38' and which further include a stopper "S", preferably slideably mounted onto the wire 34 in the

vicinity of the transition from a curved wire portion, to the relatively straight extension 38'. The stopper is between discrete springs 26 and 26¹ and held in place thereby. This embodiment is particularly advantageous for anastomosing a relatively thin-walled vessel to a relatively thick-walled vessel (e.g. the aorta or other large vessel), where an extension acts to prevent the relatively thin-walled vessel from sliding into the anastomosis site and out of the preferred position where it is to be fixed, as is illustrated in Figure 6F.

For example, this fastener design may be embodied by a 6-0 wire (wire 34) having a cross-sectional thickness of about 0.045 inches, which, in the closed configuration shown, forms an inner loop having a diameter D₁ of about 0.060 inches and an outer loop dimension D₂ of about 0.065 inches. In the open configuration the fastener forms a U-shape with a depth of the U-shape being about 0.07-0.09 inch (1.5 to 2 mm).

It is to be understood that the fasteners may have undeformed or deformed configurations different than those shown herein without departing from the scope of the invention. In addition, a locking clip (not shown) may also be attached to connect the ends of the fastener (such as fastener 20, 40, 41, 43, 43¹, 43¹¹, 43¹¹¹) when the fastener is in its closed position to prevent possible opening of the fastener over time. The locking clip may also be integrally formed with one end of the fastener.

As shown in Fig. 3C, wire 34 is surrounded by spring or coil 26 which, along with the locking device 28, restrains the wire in its deformed configuration. Coil 26 comprises a helical wire forming a plurality of loops which define a longitudinal opening 44 for receiving the shape memory alloy wire 34. Coil 26 may be formed from a platinum alloy wire having a cross-sectional diameter of approximately 0.0005-0.005 inch, for example. The helical wire may have other cross-sectional shapes and be formed of different materials. Coil 26 is preferably sized so that when in its free (uncompressed state) it extends the length of wire 34 with one end adjacent to enlarged portion 36 at the proximal end of the wire and the other end adjacent to enlarged portion 38 at the distal end of the wire. It is to be understood that the coil may not extend the full length of the wire. For example, a flange or similar device may be provided on an intermediate portion of wire 34 to limit movement of the coil along the length of the wire.

When coil 26 is in its free state (with the wire in its undeformed configuration), loops of the coil are generally spaced from one another and do not exert any significant

force on the wire 34 (Figs. 3A and 3B). When the coil 26 is compressed (with wire 34 in its deformed configuration), loops of the coil on the inner portion 46 of the coil are squeezed together with a tight pitch so that the loops are contiguous with one another while loops on the outer portion 48 of the coil are spaced from one another (Fig. 3C). This is due to the compressed inner arc length of coil 26 and the expanded outer arc length of the coil. The compression of the loops on the inner portion 46 of coil 26 exerts a force on the inner side of wire 34 which forces the wire to spread open (i.e., tends to straighten the wire from its closed configuration to its open configuration). The end of coil 26 adjacent enlarged portion 36 is held in a fixed position relative to wire 34. The opposite end of coil 26 is free to move along wire 34 and is held in place when the coil is in its compressed position by locking device 28. It should be understood, however, that a coil (not shown) having sufficient stiffness, for example, may be used where adjacent loops do not contact one another when the coil is compressed to force wire 34 into an open position.

Referring to Figs. 7A-7C, one embodiment of a releasable locking device or release mechanism, is shown. Releasable locking device 28a is adapted for releasably coupling a fastener (such as any of the fasteners shown in Figs. 3-6) to a flexible member (such as flexible member 18, 18¹ or 18¹¹) is shown and generally designated with reference numeral 28a. Release mechanism 28a comprises a flexible tubular member 50 having a distal end portion 52 and is shown with a tapered section or sleeve 2 (or 56), which in turn is coupled to the flexible member. Tapered section or sleeve 2 (or 56), which provides a transition between the flexible member and fastener for insertion of the fastener and locking device through tissue, may be a separate member coupled to tubular member 50 or be formed integrally therewith. Tubular member 50 further includes a proximal end portion 54 releasably attached to wire 34. In this manner, release mechanism 28a releasably couples the flexible member and needle to the surgical fastener such as fastener 20. In addition to releasably coupling the flexible member and needle to the fastener, the locking device or release mechanism compresses coil 26 to bias the fastener or surgical clip 20 in its open configuration. Although a straight tapered section is shown in Figs. 7A and 7C, the tapered section may be curved as well as shown in Fig. 1 and generally designated with reference numeral 56. More specifically, one may use a straight or curved tapered section in any of the tissue connector assemblies disclosed herein. When a curve is used, it preferably is

sufficiently curved to facilitate passing the tissue connector assembly through connecting tissue in an anastomosis, for example. Tapered portion 2 or 56 may be formed from a metal alloy such as stainless steel or a suitable polymeric material and may be solid or in the form of a sleeve as noted above. It may be flexible. Generally, the tapered section 2 (or 56) or any other tapered section gradually diminishes in diameter to provide a smooth, non-stepped transition between the relatively small diameter of the flexible member to the larger diameter of locking device 28 such as locking device 28a. The flexible member such as flexible member 18 may be swaged into the tapered section, or a heat shrink plastic covering may hold the flexible member in place. The locking device may also be curved.

Tubular member 50 is movable between a locked position (Figs. 7A and 7B) for holding coil 26 in its compressed position and wire 34 in its deformed position, and an unlocked position (Fig. 7C) for inserting or releasing the wire and coil. Referring to Figs. 7B and 7C, three slots 58 are shown formed in tubular member 50 extending from the proximal end 54 of the member and along at least a portion of the member. Slots 58 are provided to allow the proximal end 54 of tubular member 50 to open for insertion and removal of wire 34. It is to be understood that the number of slots 58 and configuration of the slots may vary, or tubular member 50 may be formed to allow expansion of proximal end 54 without the use of slots.

Proximal end 54 of tubular member 50 includes a bore 62 having a diameter slightly greater than the outer diameter "d" of wire 34, but smaller than the diameter of enlarged portion 38 at the distal end of the wire and the outer diameter of the coil 26. Bore 62 extends into a cavity 64 sized for receiving the enlarged portion 38 of wire 34. Tubular member 50 may be described as having an annular flange 61 for releasably securing enlarged portion 38. As shown in Fig. 7C, upon application of an inwardly directed radial squeezing force on the tubular member 50, proximal end 54 of the tubular member is opened to allow for insertion or removal of wire 34. When the force is released, the tubular member 50 moves back to its locked position and securely holds wire 34 in place and compresses the coil 26 as shown in Fig. 7A. A disc 51 may be inserted into tubular member 50 to act as a fulcrum and cause the proximal end 54 of the tubular member to open. Alternatively, disc 51 may be integrally formed with tubular member 50. As shown in Fig. 7A, the length ℓ of the bore 62 or flange 61 determines the amount of compression

of the coil, which in turn determines the amount of deformation of wire 34. The greater the length ℓ of bore 62, the greater the compression of coil 26 and the more straightening of wire 34 will undergo. The compression of coil 26 is preferably limited so that wire 34 is not stressed beyond its yield point. This allows wire 34 to revert back to its original undeformed configuration and apply sufficient pressure to hold the connected tissue together.

An alternate embodiment of the restraining device is shown in Fig. 8, and generally indicated with reference numeral 70. The restraining device 70 is used with a tubular (hollow) shape memory alloy wire 72 (having a memory loop shape) and comprises an elongated member (or mandrel) 74 sized for insertion into the wire or tube. The mandrel 74 is preferably formed from a material which is stiffer than the material of the wire 72 so that upon insertion of the mandrel into the wire, the wire is deformed into its open position. The restraining device 70 includes a stop 76 located at the proximal end of the wire 72 and which may be attached thereto such as by gluing, swaging or welding. The stop operates to prevent the fastener from being pulled through the tissue, and limits axial movement of the mandrel 74 in the proximal direction (to the right as viewed in Fig. 8). The distal end of the mandrel 74 is attached to the suture 18 and includes a tapered portion 78. The tapered portion 78 may be a sleeve or may be solid and may be formed from any suitable metal or polymeric material, for example. It is to be understood that other types of restraining devices may be used without departing from the scope of the invention.

Another tissue connector assembly is shown in Fig. 9 and generally indicated with reference numeral 100. The tissue connector assembly 100 is the same as the first embodiment 10 except that a needle 102 is attached directly to a locking device 104 with the suture 18 of the first embodiment being eliminated. The tissue connector assembly 100 includes needle 102 (which can be the same as needle 16), a restraining device 108, and a fastener 110. Fig. 9 shows the tissue connector assembly 100 with the fastener in its open (deformed) configuration. Fastener 110 may be the same as the fasteners 20, 40, 41, 43, 43¹, 43¹¹, or 43¹¹¹ described herein and shown in Figs. 3-6, for example.

The restraining device 108 comprises a coil 112 (which may be the same as the coils described herein) and the locking device 104. The locking device 104 may be the same as any locking device, except that the distal end is configured for attachment directly

to the needle 102. The needle 102 may be integrally formed with the locking device 104 or may be swaged, welded, threadably attached, or attached by any other suitable means to the locking device. The restraining device also may be the same as described restraining devices 28a, 28b and 28c, for example, or restraining device 70 as shown in Fig. 8.

5 As noted above, the tissue connector assemblies 10, 100 have many uses. They may be especially useful for minimally invasive surgical procedures including creating an anastomosis between a vascular graft 12 and an artery 14 (Figs. 2A-2G). The anastomosis may be used to replace or bypass a diseased, occluded or injured artery. A coronary bypass graft procedure requires that a source of arterial blood flow be prepared for subsequent
10 bypass connection to a diseased artery. An arterial graft may be used to provide a source of blood flow, or a free graft may be used and connected at the proximal end to a source of blood flow. Preferably, the source of blood flow is one of any number of existing arteries which may be dissected in preparation for the bypass graft procedure. In many instances it is preferred to use the left internal mammary artery (LIMA) or the right internal mammary
15 artery (RIMA), for example. Other vessels which may be used include the saphenous vein, gastroepiploic artery in the abdomen, radial artery, and other arteries harvested from the patient's body as well as synthetic graft materials, such as DACRON® (polyester fibers) or GORETEX® (expanded polytetrafluoroethylene). If a free graft vessel is used, the upstream end of the dissected vessel, which is the arterial blood source, will be secured to
20 the aorta to provide the desired bypass blood flow, as is well known by those skilled in the art. The downstream end of the graft vessel is trimmed for attachment to an artery, such as the left anterior descending coronary (LAD). It is to be understood that the anastomosis may be formed in other vessels or tissue.

Figures 2A-2F show an exemplary use of the tissue connector assemblies 10, 100
25 for connecting a graft vessel 12 to an artery 14 (target vessel). In this example, two tissue connector assemblies 10 are used to make connections at generally opposite sides of the graft vessel and tissue connector assemblies 100 are used to make connections between those made with assemblies 10 (Fig. 2E). The procedure may be accomplished with a beating heart procedure with the use of a heart stabilizer to keep the heart stable, for
30 example. The procedure may also be performed endoscopically.

The patient is first prepped for standard cardiac surgery. After exposure and control of the artery 14, occlusion and reperfusion may be performed as required. An arteriotomy is performed on artery 14 to provide an opening for receiving a graft vessel. After the snared graft vessel 12 has been prepared and made to the appropriate length as would be conventional in the art, a tissue connector assembly 10 is attached to the free end of the graft vessel along an edge margin of the vessel. In order to attach the connector assembly 10, the surgeon grasps the needle 16 with a needle holder (e.g., surgical pliers, forceps, or any other suitable instrument) and inserts the needle 16 into the tissue of the graft vessel 12 in a direction from the exterior of the vessel to the interior of the vessel. The surgeon then releases the needle 16 and grasps a forward end of the needle which is now located inside the graft vessel 12 and pulls the needle and a portion of the suture 18 through the vessel. The needle 16 is passed through an opening 120 formed in the sidewall of the artery 14 and inserted into the tissue of the artery in a direction from the interior of the artery to the exterior of the artery. The surgeon then grasps the needle 16 located outside the artery 14 and pulls the needle and a portion of the suture 18 through the arterial wall. A second tissue connector assembly 10 may be inserted at a location generally 180 degrees from the location of the first tissue connector in a conventional "heel and toe" arrangement.

Once the tissue connector assemblies 10 are inserted, the graft vessel 12 is positioned above and aligned with the opening 120 in the sidewall of the artery 14 (Fig. 2A). A section of each suture 18 is located between the graft vessel 12 and artery 14. The fasteners 20 and needles 16 are pulled generally away from the artery 14 to reduce the length of the suture 18 (eliminate slack of the suture) between the vessel 12 and artery and "parachute" the vessel onto the artery (Fig. 2B). The needles 16 are then pulled away from the artery 14 until each fastener 20 is positioned within the graft vessel 12 and artery with one end of each fastener 20 extending from the vessel and the opposite end of each fastener extending from the artery (Fig. 2C). The edges of the graft vessel 12 and artery 14 are positioned adjacent one another to form a continuous interior and exterior surface along the mating portions of the vessel and artery. As shown in Fig. 2F, the tissue is compressed within fastener 20 where the graft and arteriotomy edges may be abutted or everted as is known in the art.

A surgical instrument (e.g., needle holder) is used to radially squeeze each locking device 28 to release the locking device from the fastener 20. Upon removal of the locking device 28, the coil 26 moves to its free uncompressed state which allows the wire 34 to return to its original undeformed closed position (Fig. 2D). As the wires 34 move to their closed position the adjacent tissues of the graft vessel 12 and artery 14 which were previously pulled together during the parachuting of the graft vessel onto the artery, are squeezed together to securely engage the graft vessel and artery (Figs. 2E and 2F). It should be noted that as the locking device 28 is squeezed two steps are accomplished. The fastener 20 is released from the locking device 28, thus allowing the coil 26 to uncompress and the wire 34 to move to its closed configuration, and the needle 16 is released from the fastener. Thus, in this embodiment, the locking device 28 provides for simultaneous actuating closure of the fastener 20 and release of the needle 16 from the fastener.

The tissue connector assemblies 100 are subsequently inserted at circumferentially spaced locations around the periphery of the graft vessel to sealingly fasten the graft vessel 12 to the artery 14. The needle 102 of the fastener 100 is inserted into the graft vessel 12 from the exterior surface of the graft vessel and pushed through the graft vessel and artery 14 tissue. The needle holder is then used to pull the needle 102 through the arterial wall. An instrument (same needle holder or other suitable instrument) is used to apply a squeezing force to the locking device 104 to release the wire and coil 112 from the needle 102. This allows the coil 112 to move to its uncompressed configuration and the wire to move to its closed position. It should be noted that the tissue connector assemblies 10 may remain in their open position while the tissue connector assemblies 100 are inserted into the tissue and moved to their closed position. The locking devices 28 of the tissue connector assemblies 10 may subsequently be removed from the fasteners 20 to allow the fasteners to move to their closed position. The number and combination of tissue connectors assemblies 10, 100 required to sealingly secure the connecting tissues together may vary. For example, only tissue connector assemblies 10 may be used to complete the entire anastomosis.

Although the coil 26 is shown remaining on the wire (Fig. 2D), it is to be understood that the coil 26 may also be removed from the wire 34, leaving only the wire in the connected tissue.

As an alternative to inserting tissue connector assemblies 10 at "heel and toe" locations described above, a number of tissue connectors 10 may be inserted generally around the location of the heel. The graft vessel may then be pulled towards the artery to determine whether the opening formed in the sidewall of the artery is large enough before completing the anastomosis.

The graft vessel 12 may also be parachuted onto the artery 14 in the method shown in Fig. 2G. The needle is inserted into the graft vessel 12 and artery 14 as described above and the suture 18 is pulled through the vessel so that the fastener 20 is positioned within the vessel and artery. The needles 16 are then pulled away from the artery 14 to "parachute" the graft vessel 12 onto the artery. The anastomosis may then be completed as described above.

Although the suturing procedure has been described for an end-to-side anastomosis, it should be appreciated that the procedure is applicable to an end-to-end and side-to-side anastomosis, connecting various tissue structures including single and multiple tissue structures, and puncture sites, and connecting tissue to a prosthetic graft or valve, for example.

It will be observed from the foregoing that the tissue connector assemblies of the present invention have numerous advantages. Importantly, the assemblies are easier and faster to apply than conventional sutures which require tying multiple knots. The assemblies also may be used in minimally invasive procedures including endoscopic procedures.

According to another embodiment of the invention, multiple tissue piercing members may be provided. More specifically, tissue connecting assemblies constructed according to the present invention may include a plurality of tissue piercing or penetrating members coupled to a surgical fastener. The multiple piercing member construction facilitates threading ends of the assembly from inner to outer wall(s) of material, such as tissue, which may eliminate or minimize the possibility of dislodging material, such as plaque, from the inner wall of calcified arteries, for example, as will become more apparent from the description provided below. In a preferred embodiment, two piercing members, each of which may comprise a needle, are releasably coupled to a fastener. One or both of the piercing members may be attached to a flexible member, such as a suture,

which in turn is releaseably coupled to the fastener. Double and single flexible member embodiments are illustrated in Figs. 10 and 17, respectively. The coupling between the flexible member (and, thus, the piercing member) and the fastener may be constructed to actuate closure of the fastener upon release of the flexible member (or piercing member).

5 For example, the coupling may hold a compression spring (which is positioned around a fastener) in a compressed state to brace the fastener open and releaseably lock or secure the fastener to the flexible member (or piercing member).

Fig. 10 illustrates one embodiment of a tissue connector assembly with multiple tissue piercing members in accordance with the present invention. Referring to Fig. 10, a
10 tissue connector assembly 11, which generally comprises tissue piercing or penetrating members 16 and 17, flexible members 18 and 19, and a fastener 20 (e.g., a surgical clip) is shown. A restraining device, generally indicated at 24 and comprising a spring (or coil) 26 and a locking device (or coupling member) generally indicated at 28, is connected to fastener 20 for holding the fastener in a deformed or open configuration as will be further
15 described below. Although a particular fastener and accompanying restraining device is shown in Fig. 10, it should be understood that any suitable fastener can be used, including but not limited to the alternate fastener configurations described herein.

Penetrating or piercing member 17 may be made in accordance with the description provided above in connection with penetrating member 16, and, thus may, for example, be
20 in the form of a needle (such as a 7-0 or 8-0 needle) having a sharp pointed tip 31 at its distal end for penetrating tissue. Members 16 and 17 may be the same or differ from one another. Flexible members 18 and 19 may have the same construction. Accordingly, flexible members 18^I or 18^{II} may be substituted therefor.

Figs. 11A, 11B and 11C illustrate another release mechanism which is generally
25 designated with reference numeral 28b. Figs. 11A and 11B show the release mechanism in a locked position, and Fig. 11C shows the release mechanism in an unlocked position. Release mechanism 28b comprises a tubular member 80, which has proximal and distal ends 88 and 89, respectively. Tubular member 80 further includes bore 82 formed therein and a cavity or recess 84 extending radially outward from bore 82 into the tubular member.
30 Recess 84 is configured to receive enlarged portion 38 or wire 34 as best illustrated in Fig. 11A. Recess 84 and bore 82 form an annular flange 86, which has an inner diameter less

than that of enlarged portion 38 and, thus, resists removal of the enlarged portion. In the embodiment shown in Fig. 11A-C, three slots 87 are formed in tubular member 80 as in the embodiment shown in Figs. 7A-C. The slots extend longitudinally from the proximal end 88 of tubular member 80 and form fingers 81, which radially expand and release wire 34 upon radial compression of the tubular member as shown in Fig. 11C and as described above in connection with release mechanism 28a. In this embodiment, however, enlarged portion 38 forms a fulcrum. Although three equiangularly spaced slots, which extend parallel to the longitudinal axis are shown as in release mechanism 28a, the number and configuration of the slots may vary, or the tubular member may be formed to allow expansion of the proximal end portion without the use of slots. A tapered section 2 also may be provided as described above in connection with release mechanism 28a.

The release mechanism is generally indicated with reference numeral 28c in Figs. 12A-12E where Figs. 12A-C show the mechanism coupled with a fastener, and Figs. 12D and 12E show the release mechanism depressed for release of the fastener. Locking device or release mechanism 28c comprises a plurality of substantially rigid strands, preferably wires 106, arranged substantially parallel to one another and circularly about a longitudinal axis of the aligned strands, to form a tube-like configuration, as can be seen in the cross-sectional view of Fig. 12C and the perspective view in Fig. 12A. Alternatively, strands 106 may be cables or some other substantially rigid strand elements arranged in the same manner as the wires shown in Figure 12C. Upon arrangement into the circular configuration, the hidden end portions 106a of the strands are coupled to tapered section 2, which is coupled to a piercing member or needle through a flexible member such as flexible member 18.

Preferably, a rod 162 extends from tapered section 2 to facilitate fixation of the strands thereto. The coupling of the strands to tapered section 2 is preferably accomplished by gluing or soldering to rod 162, although other equivalent or similar known joining techniques may be employed (e.g. welding, threadably attaching, etc). Similarly, rod 162 is preferably glued, soldered or threaded into the needle or transition element. In an alternate arrangement, the flexible member may extend through tapered section 2 and form a substitute structure for rod 162. This may be preferred when the flexible member is a metal wire.

The end portions 106b of the strands in the vicinity of the fastener strands include notches 109 which are formed into the strands to a depth equal to approximately half the diameter of the strand 106. When the strands are arranged in the circular configuration described above, the notches 109 form a chamber 108 configured for receiving and holding enlarged portion 38. Although enlarged portion 38 is shown as having a spherical shape, it may have other shapes including a barrel shape, or other shape that may be easily grasped and easily released. The notches are preferably placed about .015" from the free ends of the strands, but this distance, of course, can be modified, depending upon the amount of compression of spring 26 that is desired when ball 38 is inserted into and held by notches 109.

After placement of ball 38 within chamber 108 formed by notches 109, a shrink wrap layer, preferably a shrink tubing 110 may be provided over at least free end portions 106b of wires or strands 106, and the tubing heated to compress against strands 106 and hold them in place against ball 38, preferably symmetrically against ball 38. Together, tubing 110 and strands 106 effectively hold ball 38 captive within notches 109. Alternatively, other plastic or elastic restraining members may be mounted around the distal portions of the wires or strands to aid in maintaining them in place, preferably symmetrically against ball 38. Still further, strand members may be designed with an elastic spring force sufficient to maintain notches 109 in place with sufficient force to maintain the ball 38 captive therein under the tensile forces normally experienced during a suturing procedure. Although a seven strand embodiment is shown, it should be understood that fewer or more than seven strands may be used. The number of strands may vary depending on, for example, the size of the clip or the size of the strands. Typically, the number of strands may range from two to ten. In a coronary anastomosis, the number of strands preferably will range from five to seven although other numbers may be used.

In assembling, enlarged portion 38 of wire 34 is placed in chamber 108. Tubing 110 is wrapped around at least a portion of the strands (as shown in the drawings) and heated to maintain enlarged portion 38 captive within the cavity formed by the strands. Compression coil or spring 26 is slid over wire 34 and compressed against portions 106b such that the fastener is in its open configuration. Enlarged portion 36 may then be formed or attached to wire 34 to maintain the fastener in its open configuration.

Release mechanism 28c is movable between a locked position (Figs. 12A-12C) and an unlocked position (Figs. 12E and 12F). In the locked position the ball 38 is held within notches 109 and consequently, coil 26 is held in its compressed position, thereby maintaining fastener wire 34 in its deformed or open position. In the unlocked position, ball 38 is released from the notches, thereby allowing the coil 26 to expand, which causes the fastener wire 34 to close. The closure conformation of the wire may be characterized by any of those described above with reference to Figs. 3-6, for example.

Movement of the release mechanism to the open position is accomplished by applying a compressive force to the shrink tube 110 and bundle of strands 106, as shown in Figs. 12D and 12E. Advantageously, the compressive force may be applied at any opposing locations around the circumference of the shrink tube as long as the implement applying the force is oriented at an angle to the strands, preferably substantially perpendicular thereto, to allow the implement to traverse the strands so as to deform the positions thereof when the force is applied. For example, needle holder 111 could be rotated 90° (or virtually any other angle) with respect to the strands 106 as shown in the plane of the drawing, while retaining the capability of deforming the strands to an open position upon application of a compressive force. The compressive force is preferably applied using a standard needle holder 111 or forceps, although other tools could be used, preferably those with applicators narrower than the length of the shrink tube 110. As shown, the strands or wires 106 get distorted from their circular configuration under the compression. This change in shape stretches the shrink tube 110 from a circular configuration to a somewhat elliptical configuration, and removes some of the notches 109 from contact with ball 38, thereby permitting removal of ball 38 from within the chamber previously formed by notches 109 in the closed position.

Referring to Fig. 12F, release mechanism 23c also may be used to releasably couple the other end of the fastener to another flexible member such as flexible member 19, which in turn, is coupled to a needle such as needle 17 as shown in Fig. 1. In this arrangement, a member or stopper 115, which may be annular, is secured to the other end of the fastener or wire 34 to prevent enlarged portion 36 from passing through the compression spring upon release from release mechanism 23c. Other release mechanisms, which provide synchronized release of both needles illustrated in Fig. 10 or 17, also can be used.

Figs. 13A-13F illustrate synchronized fastener release systems. Referring to Figs. 13A-13C, a first synchronized release system is shown in a coupled and decoupled state, respectfully. Although one release mechanism is shown as corresponding to release mechanism 28c, release mechanisms 28a or 28b or any release mechanism which releaseably couples the flexible member or needle to the surgical fastener and effects compression of coil 26 also may be used. At the other end of the fastener or wire 34, a release mechanism which responds to the compressive state of coil 26 and releases the fastener or wire 34 upon release of compressive forces on the coil is shown and generally designated with reference numeral 29a. Release mechanism 29a comprises two members 121 each having a recess 122 formed therein and arranged to form chamber 124 when members 121 are aligned as shown in Fig. 13A. Recesses 122 are configured to retain enlarged portion 36, which is shown with a cylindrical configuration, but may have a spherical or other suitable shape for operatively associating with a suitably configured chamber. Further, members 121 may have semicircular transverse cross sections or some other combination of transverse shapes that can collectively provide the desired chamber to retain enlarged portion 36. The number of members 121 also may vary as would be apparent to one of ordinary skill.

Release mechanism members 121 have tapered ends 126, which are configured for positioning between coil 26 and fastener wire 34 as shown in Fig. 13A. When tapered ends 126 are so positioned and coil 26 is in a compressed state, coil 26 holds tapered ends 126, which are normally biased away from each other as shown in Fig. 13C, sufficiently together to retain enlarged portion 36 within chamber 124. When release mechanism 28c is actuated (e.g., radially compressed) to release enlarged portion 38 of fastener wire 34, coil 26 assumes its relaxed state, thereby releasing tapered ends 126 of release mechanism 29a from the coil and allowing the tapered ends to radially expand and release enlarged portion 36 of fastener wire 34 as shown in Fig. 13C. Accordingly, both needles and flexible members may be decoupled from the fastener when release mechanism 28c is actuated.

Figs. 13D-13F show another synchronized fastener system which is the same as the system shown in Figs. 13A-13C with the exception of release mechanism 29b and the cooperating portion of the fastener or wire 34 being substituted for release mechanism 29a. In this embodiment, an annular member or stopper 115, which may be annular, is slidably

coupled to fastener wire 34. Member 115 is configured to resist passage of coil 26 thereover. Accordingly, member 115 may have an outer diameter slightly greater than at least the portion of the coil adjacent thereto. A tapered or frustoconical member 3' is secured to an end of fastener wire 34, which need not include an enlarged portion. Member 3' is the same as member 3 with the exception that member 3' has a channel 134 for receiving flexible member or suture 19. Channel 134 extends radially outward from bore 132, which is formed through member 3', for receiving the fastener or wire 34.

Flexible member 19 is threaded through channel 134 and between tapered member 3' and annular member 115. When coil 26 is in a compressed state as shown in Fig. 13D, the coil urges member 115 toward tapered member 3' and compresses flexible member 19 therebetween. In this manner, flexible member 19 is secured to the fastener or wire 34. When release mechanism 28c is actuated (e.g., radially compressed) to release enlarged portion 38 of the fastener or wire 34, coil 26 assumes its relaxed state so that annular member 155 may slide away from tapered member 3' and release flexible member 19. Accordingly, both needles and flexible members may be removed from the fastener when release mechanism 28c is actuated. Although a metal flexible member may be used, a polymeric flexible member may be preferred.

Figs. 14A and 14B show another release mechanism generally indicated with reference numeral 29c. Release mechanism 29c includes a sleeve 142, which is slidably mounted over flexible member 19 so that it can be positioned over the flexible member and the fastener or wire to releasably hold the flexible member and the fastener together. The end portion of the flexible member opposite the needle and the end portion of the fastener or wire to be engaged therewith may be configured to provide interlocking engagement therebetween. In the embodiment shown in Figs. 14A and 14B, the flexible member, which preferably is metal in this example, and the fastener or wire end portions have mating flange and groove configurations. Flexible member 19 includes groove 144a and flange 146a, which mate with or interlockingly engage groove 144b and flange 146b, which are formed in wire 34. When sleeve 142 is moved away from the fastener or wire, the coupling becomes unrestrained and the flexible member and the fastener or wire can be readily separated by removing flanges 146a and 146b from grooves 144a and 144b as shown in Fig. 11B. Member 115 may be secured to fastener wire 34 to prevent the end of

coil 26 adjacent to groove 144b and flange 146b from sliding thereover. Member 115 also may be described as a stopper for spring 26.

Figs. 15A and 15B show another release mechanism, which is generally designated with reference numeral 29d. In this embodiment, tapered member 3 is provided with a bore for receiving both flexible member 19 and the fastener or wire 34. Member or collar 115 may be fixedly secured to the fastener or wire 34 to resist coil movement over the wire and toward the flexible member. The fastener or wire also may be fixedly secured to the inner wall of tapered member 3 by, for example, gluing or welding. One end of the flexible member is tied into a knot such as knot 150. The knot is packed into the bore 152 and the tapered member is swaged or crimped as shown in Figs. 15A and 15B to secure the knot in the bore. The flexible member is cut as shown in Fig. 15B to decouple the flexible member from the fastener.

Figs. 16A and 16B illustrate a further release mechanism, which is generally designated with reference numeral 29e. Release mechanism 29e generally comprises a release member having a cavity formed therein to receive the fastener or wire 34 and a portion configured for severing the fastener wire. This advantageously eliminates the need for a separate cutting tool to separate the suture or needle from the fastener. One example of such a release member is shown as release member 160. Release member 160 has one end which is fixedly secured to tapered member 3 to which flexible member 19 is secured. Alternatively, members 3 and 160 may be integrally formed. Release member 160 is configured to form a cavity 162 therein and may be in the form of a sleeve. Member 160 includes annular flange 164 through which fastener wire 34 is received. Annular flange 164 includes an annular lip 166, which forms a cutting surface or annular blade. Release member 160 also may include an opening for receiving flexible member 19 therethrough as shown in Figs. 16A and 16B. In this example, release member 160 can be fixedly secured to flexible member 19, which, in turn, can be fixedly secured to tapered member 3. Of course, it should be understood that members 160 and 3 can be directly secured to one another or integrally formed as a single piece. When release member 160 is radially compressed as shown in Fig. 16B, annular lip severs fastener wire 34 and decouples flexible member therefrom. Fastener wire 34 may be provided with annular groove 168 to enhance wire fracture. Release member 160 or annular lip 166 may be 400 series stainless

steel or tool steel to facilitate hardening. Other materials that tend to provide an effective cutting tool also may be used. Release member 160, however, should comprise material that provides the desired flexibility. Further, it should be understood that although release member 160 is shown with a generally cylindrical configuration, other configurations may be used. In assembly, member 115, which may be annular, may be swaged, glued or welded to wire 34 to compress coil 34 after the other end of wire has been secured to a locking device or coupling so that the fastener opens as may be done in the embodiments of Figs. 14A and B and 15A and B. Wire 34 may be preformed with groove 168 or the groove formed prior to sliding member 160 over wire 34 so as to engage blade 166 with the groove.

It is to be understood that locking devices other than those described above may be used with the single or double needle embodiment described herein without departing from the scope of the invention. For example, a locking device (not shown) may comprise a tubular member having an opening formed in a sidewall thereof for receiving an end portion of the wire. The end of the wire may be bent so that it is biased to fit within the opening in the sidewall of the tubular member. An instrument, such as a needle holder may then be used to push the wire away from the opening in the tubular member and release the wire from the tubular member. Various other types of locking devices including a spring detent or bayonet type of device may also be used. Further, the fastener or wire end portions may be configured differently than that shown. For example, one or both of the fastener or wire end portions may be provided with grooves instead of enlarged portions and the release mechanisms or locking device arms, such as, for example, fingers 81 or strands 106, may be provided with projections to releaseably engage with the grooves. It is further noted that the release mechanisms disclosed interchanged in the single and double needle embodiments. For example, release mechanisms 28a, 28b and 28c may be used for release mechanism 29 with the inclusion of a fixed stop 115. Release mechanisms 28a, 28b and 28c are also interchangeable in the single needle assemblies.

Fig. 17A is a front view of another embodiment of a tissue connector assembly of the present invention which is generally designated with reference numeral 211. Tissue connector assembly 211 is the same as tissue connector assembly 11 with the exception that locking device or release mechanism 28 is directly connected to needle 16. Although any

of the release mechanisms 28a-c may be used to couple the fastener to needle 16, release mechanism 28c is shown in Fig. 14B for purposes of illustrating a connection between a locking device and needle 16.

Referring to Fig. 17B, rod 162 extends from needle 16. Rod 162 and needle 16 may be integrally formed or be separate elements secured which are fixed to one another. The coupling of strands 106 to the needle is preferably accomplished by gluing or soldering to the rod 162, although other equivalent or similar known joining techniques may be employed (e.g. welding, threadably attaching, etc). Similarly, when the rod and needle are discrete elements, the rod is preferably glued, soldered or threaded into the needle. Alternately, rod 162 may extend from or be affixed to a transition element which in turn is affixed to needle 16.

Figures 18A-18D diagrammatically illustrate a method of aligning and connecting graft and target vessels, such as connecting a graft vessel 12 to an artery 14 (target vessel) using tissue connector assemblies 11 and 100. In this example, two tissue connector assemblies 11 are used to make connections at generally opposite sides of the graft vessel and tissue connector assemblies 100 are used to make connections between those made with assemblies 11. The procedure may be accomplished with a beating heart procedure with the use of a heart stabilizer to keep the heart stable, for example. The procedure may also be performed endoscopically. It also should be understood that tissue connector assemblies 211 may be substituted for assemblies 11.

The patient is first prepped for standard cardiac surgery. After exposure and control of artery 14, occlusion and reperfusion may be performed as required, an arteriotomy is performed on artery 14 to provide an opening 120 for receiving a graft vessel. After the snared graft vessel 12 has been prepared as would be apparent to one of ordinary skill in the art, a tissue connector assembly 11 is attached to the free end of the graft vessel along an edge margin of the vessel. In order to attach the connector assembly 11, the surgeon grasps needle 16 with a needle holder (e.g., surgical pliers, forceps, or any other suitable instrument) and inserts needle 16 into the tissue of graft vessel 12 in a direction from the interior of the vessel to the exterior of the vessel. The surgeon then releases the needle 16 and grasps a forward end of the needle which is now located outside graft vessel 12 and pulls the needle and a portion of suture 18 through the vessel. Needle 17 is passed through

opening 120 formed in the sidewall of the artery 14 and inserted into the tissue of the artery in a direction from the interior of the artery to the exterior of the artery. The surgeon then grasps needle 17 located outside the artery 14 and pulls the needle and a portion of suture 19 through the arterial wall. A second tissue connector assembly 11 may be inserted as described above at a location generally 180 degrees from the location of the first tissue connector in a conventional "heel and toe" arrangement.

Once the tissue connector assemblies 11 are inserted, graft vessel 12 is positioned above and aligned with opening 120 in the sidewall of the artery 14 (Fig. 18A). A section of each assembly is located between graft vessel 12 and artery 14. The needles 16 and 17 are pulled generally away from the artery 14 to reduce the length of the sutures 18 and 19 (eliminate slack of the sutures) between vessel 12 and artery and "parachute" the vessel onto the artery (Fig. 18B). The needles 17 are then pulled away from the artery 14 until each fastener 20 is positioned within the target vessel 14 as shown in Fig. 18B. Needles 16 are then pulled away from graft 12 until the fasteners are positioned with one end of each fastener 20 extending from the vessel and the opposite end of each fastener extending from the artery (Fig. 18C). The edges of the graft vessel 12 and artery 14 are positioned adjacent one another to form a continuous interior and exterior surface along the mating portions of the vessel and artery. The tissue may be compressed as described above with reference to Fig. 2F.

A surgical instrument (e.g., needle holder) is used to radially squeeze each locking device 28 to release the locking device from the fastener 20. Upon removal of each locking device 28, each coil 26 moves to its free uncompressed state which allows fastener wire 34 to return to its original undeformed closed position (Fig. 18D). As the wires 34 move to their closed position the adjacent tissues of the graft vessel 12 and artery 14 which were previously pulled together during the parachuting of the graft vessel onto the artery, are squeezed together to securely engage the graft vessel and artery (Fig. 18E). It should be noted that as each locking device 28 is squeezed at least two steps are accomplished. The fastener 20 is released from locking device 28, thus allowing coil 26 to uncompress and the wire 34 to move to its closed configuration, and the needle 16 is released from the fastener. Thus, any of the locking devices 28 described above provides for simultaneous actuating closure of the fastener 20 and release of the needle 16 from the fastener. Further, radially

compression of release mechanisms 29 releases needles 17 and sutures 19 from the fasteners. However, if one of the synchronous release systems described with reference to Figs. 13A-13F is used, radial compression of a locking device 28 device will effect essentially simultaneous closure actuation of a respective fastener and release of needles 16 and 17 and sutures 18 and 19.

The tissue connector assemblies 100 are subsequently inserted at circumferentially spaced locations around the periphery of the graft vessel to sealingly fasten graft vessel 12 to artery 14. Needle 16 of fastener 100 is inserted into graft vessel 12 from the exterior surface of the graft vessel and pushed through the graft vessel and artery 14 tissue. The needle holder is then used to pull the needle 16 through the arterial wall. An instrument (same needle holder or other suitable instrument) is used to apply a squeezing force to the locking device 28 to release fastener 20 from needle 16. This allows coil 26 to move to its uncompressed configuration and the wire to move to its closed position. It should be noted that the tissue connector assemblies 11 may remain with their fasteners in their open position while tissue connector assemblies 100 are inserted into the tissue and moved to their closed position. The locking devices 28 of the tissue connector assemblies 11 may subsequently be removed from the fasteners 20 to allow the fasteners to move to their closed position. The number and combination of tissue connectors assemblies 11 and 100 required to sealingly secure the connecting tissues together may vary. For example, only tissue connector assemblies 11 may be used to complete the entire anastomosis.

Although coils 26 are shown remaining on the fastener or wire (Fig. 18D), it is to be understood that coils 26 may also be removed from wires 34, leaving only the wires in the connected tissue.

As an alternative to inserting tissue connector assemblies 11 at "heel and toe" locations described above, a number of tissue connector assemblies 11 may be inserted generally around the location of the heel. The graft vessel may then be pulled towards the artery to determine whether the opening formed in the sidewall of the artery is large enough before completing the anastomosis. It also should be understood that tissue connector assemblies 211 may be used instead of or in conjunction with assemblies 11.

Although the suturing procedure has been described for an end-to-side anastomosis, it should be appreciated that the procedure is applicable to an end-to-end and side-to-side

anastomosis, connecting various tissue structures including single and multiple tissue structures, and puncture sites, and connecting tissue to a prosthetic graft or valve, for example.

5 It will be observed from the foregoing that the tissue connector assemblies of the present invention have numerous advantages. Importantly, the assemblies are easier and faster to apply than conventional sutures which require tying multiple knots. The assemblies also may be used in minimally invasive procedures including endoscopic procedures.

10 All references cited above and U.S. Patent Application Serial Nos. 09/090,305 and 09/259,705 are incorporated herein by reference.

The above is a detailed description of particular embodiments of the invention. It is recognized that departures from the disclosed embodiments may be made within the scope of the invention and that obvious modifications will occur to a person skilled in the art. The full scope of the invention is set out in the claims that follow and their equivalents.

15 Accordingly, the claims and specification should not be construed to unduly narrow the full scope of protection to which the invention is entitled.

WHAT IS CLAIMED IS:

1. A tissue connector assembly comprising a flexible member and a surgical clip, said surgical clip being releasably coupled to said flexible member.

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2. The tissue connector assembly of claim 1 wherein said flexible member comprises a suture.

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3. The tissue connector assembly of claim 1 further including a needle, said needle being coupled to said flexible member.

4. The tissue connector assembly of claim 1 further including a tapered portion extending between said surgical clip and flexible member.

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5. The tissue connector assembly of claim 4 wherein said tapered portion is curved.

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6. The tissue connector assembly of claim 1 further comprising a locking device, said locking device having a locked position where said surgical clip is coupled to said flexible member and an unlocked position where said surgical clip is released from said flexible member.

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7. The tissue connector assembly of claim 1 wherein said surgical clip comprises a wire.

8. The tissue connector assembly of claim 7 wherein said wire is tubular.

9. The tissue connector assembly of claim 7 wherein said wire has a generally circular transverse cross-section.

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10. The tissue connector of claim 7 wherein said wire comprises shape memory material.

11. The tissue connector assembly of claim 7 wherein said wire has a first end portion, a second end portion, and an elongated member therebetween, said first end portion being coupled to said flexible portion, said second end portion having a cross-sectional area greater than a cross-sectional area of said elongated member.

12. The tissue connector assembly of claim 1 wherein said surgical clip has an open configuration and a closed configuration.

13. The tissue connector assembly of claim 12 wherein said surgical clip is in said closed configuration when in a relaxed position.

14. The tissue connector assembly of claim 12 wherein said surgical clip is generally U-shaped when in said open configuration.

15. The tissue connector assembly of claim 12 wherein said surgical clip assumes a spiral configuration when in said closed configuration.

16. The tissue connector assembly of claim 15 wherein said surgical clip spirals around a central longitudinal axis, said surgical clip having a generally conical shape along said longitudinal axis.

17. The tissue connector assembly of claim 16 wherein said surgical clip has an inner end portion and an outer end portion, said inner end portion having a smaller radius than said outer end portion, said inner end portion of said surgical clip being coupled to said flexible member.

18. The tissue connector assembly of claim 12 further comprising a restraining device coupled to said clip and biasing said clip in said open configuration.

19. The tissue connector assembly of claim 18 wherein said restraining device comprises a coil surrounding at least a portion of said surgical clip.

5 20. The tissue connector assembly of claim 19 wherein said coil comprises a plurality of adjacent loops, said coil being compressed with said plurality of adjacent loops being spaced closer to one another along one side of said coil than along an opposite side of said coil when said surgical clip is coupled to said flexible member.

10 21. The tissue connector assembly of claim 18 wherein at least a portion of said restraining device remains on said surgical clip when said clip is released from said flexible member.

15 22. The tissue connector assembly of claim 18 wherein said surgical clip comprises a tubular wire and said restraining device comprises an elongated member positioned within said wire.

20 23. A tissue connector assembly comprising a needle, a flexible member coupled to said needle, and a locking device coupled to said flexible member and adapted for receiving a surgical fastener.

 24. The tissue connector assembly of claim 23 wherein said flexible member is a suture.

25 25. A tissue connector assembly comprising a suture having first and second end portions, a needle secured to one of said end portions, and a surgical clip coupled to the other of said end portions.

30 26. The tissue connector assembly of claim 25 wherein said clip comprises a wire.

27. The tissue connector assembly of claim 26 wherein said wire comprises shape memory material.

28. The tissue connector assembly of claim 25 wherein said clip has an open configuration and a closed configuration.

29. The tissue connector assembly of claim 28 wherein said clip is generally U-shaped when in said open configuration.

30. A method for connecting portions of material, at least one portion comprising tissue, the method comprising:

drawing multiple portions of material, at least one of which comprises tissue, together with a tissue connector assembly having a clip in an open position; and closing said clip and securing said material portions therein.

31. The method of claim 30 wherein said materials are drawn together by pulling said tissue connector assembly.

32. The method of claim 31 wherein said tissue connector assembly is pulled with at least a portion of said tissue connector assembly positioned in said portions of material.

33. The method of claim 31 wherein said tissue connector assembly is pulled with at least a portion of said clip positioned in one of said portions of material.

34. The method of claim 30 including inserting a flexible member coupled to said clip through said portions of material, and at least one end of said tissue connector assembly is pulled to draw said materials together.

35. The method of claim 34 wherein said clip is pulled to draw said materials together.

36. The method of claim 30 wherein said tissue connector assembly is inserted into said multiple portions of material with a needle.

5 37. The method of claim 36 including simultaneously actuating closure of said clip and release of said needle therefrom.

10 38. The method of claim 36 including manipulating a portion of said tissue connector assembly to both actuate closure of said clip and release said needle from said clip.

39. A method for connecting a graft vessel to a target vessel in an anastomosis comprising:

15 inserting a tissue connector assembly through said graft and target vessels with said graft vessel being spaced from said target vessel and said tissue connector assembly having a first end extending from an exterior surface of said graft vessel and a second end extending from an exterior surface of said target vessel; and

20 pulling at least a portion of said tissue connector assembly to draw said graft vessel into contact with said target vessel.

40. The method of claim 39 further comprising inserting a second tissue connector assembly through said graft and target vessels prior to pulling at least a portion of said tissue connector assembly.

25 41. The tissue connector assembly of claim 1 including a second needle, said second needle being coupled to said surgical clip.

30 42. The tissue connector assembly of claim 41 including a second flexible member having a first portion coupled to said second needle and a second portion coupled to said clip.

43. The tissue connector assembly of claim 12 further comprising a coil surrounding said clip and a constraint extending from said clip, said clip having an enlarged portion and said coil being compressed between said constraint and enlarged portion.

5 44. A tissue connector assembly comprising a surgical fastener, which is adapted to assume a loop configuration, a first tissue piercing member and a second tissue piercing member, said surgical fastener having a first end portion and a second end portion, said first tissue piercing member being coupled to said first end portion and said second tissue piercing member being coupled to said second end portion.

10 45. The tissue connector assembly of claim 44 further including a flexible member, said flexible member having a first end portion coupled to said first tissue piercing member and a second end portion coupled to said first end portion of said fastener.

15 46. The tissue connector assembly of claim 45 further including a second flexible member, said second flexible member having a first end portion coupled to said second tissue piercing member and a second end portion coupled to said second end portion of said fastener.

 47. The tissue connector assembly of claim 46 wherein said first flexible member comprises a suture.

20 48. The tissue connector assembly of claim 46 wherein each of said flexible members comprises a suture.

 49. The tissue connector assembly of claim 46 wherein at least one of said flexible members comprises metal.

 50. The tissue connector assembly of claim 45 wherein said flexible member comprises a suture.

51. The tissue connector assembly of claim 45 wherein said flexible member comprises metal.

52. The tissue connector assembly of claim 44 wherein at least one of said tissue piercing members comprises a needle.

5 53. The tissue connector assembly of claim 44 wherein each of said tissue piercing members comprises a needle.

54. The tissue connector assembly of claim 44 further including a coupling, said first tissue piercing member and said first end portion of said surgical fastener being coupled to said coupling.

10 55. The tissue connector assembly of claim 54 wherein said coupling comprises a tubular member having movable portions and said surgical fastener includes an enlarged portion adapted for receipt in said movable portions.

56. The tissue connector assembly of claim 55 wherein said enlarged portion is spherical.

15 57. The tissue connector assembly of claim 55 wherein said movable portions comprise a plurality of strands.

58. The tissue connector assembly of claim 57 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

20 59. The tissue connector assembly of claim 57 wherein said strands comprise wires.

60. The tissue connector assembly of claim 57 wherein said strands comprise cables.

61. The tissue connector assembly of claim 54 including a second coupling, said surgical fastener second end portion and second piercing member being coupled to said second coupling.

5 62. The tissue connector assembly of claim 61 wherein said surgical fastener includes an enlarged portion and said second coupling comprises a generally tubular member having movable portions adapted to receive at least a portion of said second portion.

63. The tissue connector assembly of claim 62 wherein said movable portions comprise a plurality of strands.

10 64. The tissue connector assembly of claim 62 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

65. The tissue connector assembly of claim 61 wherein said second coupling releases the coupling between said second piercing member and said surgical fastener in response to releasing said fastener first end portion coupling.

15 66. The tissue connector assembly of claim 61 further including a coil surrounding said surgical fastener and wherein said fastener includes first and second enlarged portions and said fastener first end portion coupling and said second coupling are adapted for receipt of said fastener first and second enlarged portions, respectively, said second coupling including members having portions that have a radially outward bias and
20 extend within said coil when said coil is compressed against said second coupling.

67. The tissue connector assembly of claim 61 further including a flexible member and a coil, said flexible member having a portion coupled to said second tissue piercing member and a portion coupled to said second coupling, said coil surrounding said surgical fastener and being compressed against said second coupling, said fastener
25 including an enlarged portion and said fastener first end portion coupling being adapted for receipt of said enlarged portion, said second coupling including a first member fixedly

secured to said fastener and a second member slidably coupled to said fastener, and said flexible member being compressed between said second coupling members when said coil is compressed against said slidably coupled member.

5 68. The tissue connector assembly of claim 61 wherein said fastener includes a groove and projection and said second coupling includes a member having a groove and projection and a sleeve slidably mounted thereon, said fastener groove and projection being configured to mate with said coupling member groove and projection.

10 69. The tissue connector assembly of claim 61 further including a flexible member having a portion coupled to said second tissue piercing member and a knotted portion, said second coupling including a tubular member having a bore, said knotted portion being in said bore and said bore having a portion with a diameter less than that of a section of said knotted portion.

15 70. The tissue connector assembly of claim 61 wherein said second coupling comprises an annular blade coupled to said second piercing member, said annular blade surrounding and being secured to a portion of said surgical fastener.

 71. The tissue connector assembly of claim 44 wherein said surgical fastener comprises a surgical clip.

 72. The tissue connector assembly of claim 71 wherein said surgical clip comprises a wire.

20 73. The tissue connector assembly of claim 72 further including a coil surrounding at least a portion of said wire and having confined ends.

 74. The tissue connector of claim 72 wherein said wire comprises shape memory material.

25 75. The tissue connector assembly of claim 71 wherein said surgical clip has an open configuration and a closed configuration.

76. The tissue connector assembly of claim 75 wherein said surgical clip is in said closed configuration when in a relaxed state.

77. The tissue connector assembly of claim 75 wherein said surgical clip is generally U-shaped when in said open configuration.

5 78. The tissue connector assembly of claim 75 wherein said surgical clip assumes a spiral configuration when in said closed configuration.

79. A tissue connector assembly comprising a surgical fastener having first and second end portions, a first tissue piercing member, a second tissue piercing member, and at least one flexible member having first and second end portions, said at least one flexible member first end portion being attached to said first tissue piercing member, said at least one flexible member second end portion being coupled to said first end portion of said surgical fastener, said second end portion of said surgical fastener being coupled to said second tissue piercing member.

10 80. The tissue connector assembly of claim 79 wherein said at least one flexible member comprises a suture.

15 81. The tissue connector assembly of claim 79 wherein said at least one flexible member comprises metal.

82. The tissue connector assembly of claim 79 further including a coupling, said flexible member and surgical fastener being secured to said coupling.

20 83. The tissue connector assembly of claim 82 wherein said coupling and flexible member have outer surfaces, said coupling and flexible member being configured to form a smooth, continuous transition there between along said outer surfaces.

25 84. The tissue connector assembly of claim 82 wherein said coupling and flexible member form an interface, at least a portion of each of said coupling and flexible member adjacent to said interface having the same cross-sectional shape and dimension.

85. The tissue connector assembly of claim 82 wherein said coupling and flexible member have essentially the same cross-sectional shape and dimension.

86. The tissue connector assembly of claim 82 wherein said surgical fastener is releasably coupled to said coupling.

5 87. The tissue connector assembly of claim 82 wherein said surgical fastener includes an enlarged portion and said coupling comprises a tubular member having movable portions adapted to receive at least a portion of said enlarged portion.

88. The tissue connector assembly of claim 87 wherein said enlarged portion is spherical.

10 89. The tissue connector assembly of claim 87 wherein said movable portions comprises a plurality of strands.

90. The tissue connector assembly of claim 89 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

15 91. The tissue connector assembly of claim 89 wherein said strands comprise wires.

92. The tissue connector assembly of claim 89 wherein said strands comprise cables.

20 93. The tissue connector assembly of claim 82 including a second coupling, said surgical fastener second end portion and second piercing member being coupled to said second coupling.

94. The tissue connector assembly of claim 93 wherein said surgical fastener includes a second enlarged portion and said second coupling comprises a generally tubular member having movable portions adapted to receive at least a portion of said enlarged portion.

95. The tissue connector assembly of claim 94 wherein said movable portions comprise a plurality of strands.

96. The tissue connector assembly of claim 94 wherein a plurality of said strands include a notch for receiving a portion of said enlarged portion.

5 97. The tissue connector assembly of claim 93 wherein said second coupling releases the coupling between said second piercing member and said surgical fastener in response to releasing said fastener first end portion coupling.

10 98. The tissue connector assembly of claim 93 further including a coil surrounding said surgical fastener and wherein said fastener includes first and second enlarged portions and said fastener first end portion coupling and said second coupling are adapted for receipt of said fastener first and second enlarged portions, respectively, said second coupling including members that are biased radially inward with portions extending within said coil when said coil is compressed against said second coupling.

15 99. The tissue connector assembly of claim 93 further including a second flexible member and a coil, said second flexible member having a portion coupled to said second tissue piercing member and a portion coupled to said second coupling, said coil surrounding said surgical fastener and being compressed against said second coupling, said fastener including an enlarged portion and said fastener first end portion coupling being adapted for receipt of said enlarged portion, said second coupling including a first member
20 fixedly secured to said fastener and a second member slidably coupled to said fastener, and said flexible member being compressed between said second coupling members when said coil is compressed against said slidably coupled member.

25 100. The tissue connector assembly of claim 93 wherein said fastener includes a groove and projection and said second coupling includes a member having a groove and projection and a sleeve slidably mounted thereon, said fastener groove and projection being configured to mate with said coupling member groove and projection.

101. The tissue connector assembly of claim 93 further including a second flexible member having a portion coupled to said second tissue piercing member and a knotted portion, said second coupling including a tubular member having a bore, said knotted portion being in said bore and said bore having a portion with a diameter less than
5 that of a section of said knotted portion.

102. The tissue connector assembly of claim 93 wherein said second coupling comprises an annular blade coupled to said second piercing member, said annular blade surrounding and being secured to a portion of said surgical fastener.

103. The tissue connector assembly of claim 79 wherein said surgical fastener
10 comprises a surgical clip.

104. The tissue connector assembly of claim 103 wherein said surgical clip comprises a wire.

105. The tissue connector assembly of claim 104 further including a coil surrounding at least a portion of said wire and having confined ends.

106. The tissue connector of claim 104 wherein said wire comprises shape
15 memory material.

107. The tissue connector assembly of claim 103 wherein said surgical clip has an open configuration and a closed configuration.

108. The tissue connector assembly of claim 107 wherein said surgical clip is in
20 said closed configuration when in a relaxed state.

109. The tissue connector assembly of claim 107 wherein said surgical clip is generally U-shaped when in said open configuration.

110. The tissue connector assembly of claim 107 wherein said surgical clip assumes a spiral configuration when in said closed configuration.

111. A tissue connector assembly comprising two needles, a surgical clip and a flexible member having a portion releaseably coupled to said surgical clip and a portion coupled to one of said needles, the other one of said needles being coupled to said surgical clip.

5 112. The tissue connector assembly of claim 111 further comprising a second flexible member having a portion releaseably coupled to said surgical clip and a portion coupled to said other one of said needles.

10 113. Tissue connector apparatus comprising a wire, a tissue piercing member, a generally tubular member having first and second end portions and surrounding said wire and a coupling, said piercing member being coupled to said coupling and said coupling including members having portions that have a radially outward bias and extend within said tubular member second end portion, said tubular member second end portion being releaseably constrained.

114. The apparatus of claim 113 wherein said generally tubular member is a coil.

15 115. Tissue connector apparatus comprising a surgical fastener, a tissue piercing member, a flexible member, a coupling, and a coil, said flexible member having a portion coupled to said piercing member and a portion coupled to said coupling, said coil surrounding said surgical fastener and being compressed against said coupling, said coupling including a first member fixedly secured to said fastener and a second member
20 slidably coupled to said fastener, and said flexible member being positioned between said coupling members, and said coil surrounding said surgical fastener and having one end releaseably constrained and the other end compressed against said slidably coupled member.

25 116. Tissue connector apparatus comprising a surgical fastener, tissue piercing member and a coupling said fastener including a groove and projection and said coupling including a member having a groove and projection and a sleeve slidably mounted thereon,

said fastener groove and projection being configured to mate with said coupling member groove and projection.

5 117. Tissue connector apparatus comprising a surgical fastener, a tissue piercing member, a flexible member having a portion coupled to said tissue piercing member and a knotted portion, and a tubular member having a bore, said fastener being coupled to said tubular member and said knotted portion being in said bore, said bore having a portion with a diameter less than that of a section of said knotted portion.

10 118. Tissue connector apparatus comprising a surgical fastener, an annular blade and a tissue piercing member, said tissue piercing member being coupled to said annular blade, and said annular blade surrounding and being secured to a portion of said surgical fastener.

119. A method of decoupling multiple tissue piercing members from a surgical fastener comprising actuating release of multiple piercing members, which are coupled to a surgical fastener, essentially simultaneously.

15 120. A method of decoupling multiple tissue piercing members from a surgical fastener comprising releasing multiple tissue piercing members, which are coupled to a surgical fastener, with a single release actuator.

20 121. A method of decoupling multiple tissue piercing members from a surgical fastener including simultaneously actuating release of multiple needles from a surgical fastener.

122. The method of setting a tissue connector assembly including a surgical fastener and multiple tissue piercing members coupled thereto comprising manipulating a single portion of the tissue connector assembly to both release the tissue piercing members from the fastener and actuate closure of the fastener.

123. A method of securing portions of material together, at least one of which comprises tissue, the method comprising placing at least a portion of a first piercing member, having a surgical fastener coupled thereto, in a vessel lumen, placing at least a portion of a second piercing member, which also is coupled to the surgical fastener and where at least one of the piercing members is coupled to the surgical fastener with a flexible member, in a tubular graft, passing the first piercing member through the wall of the vessel from an interior surface thereof, passing the second piercing member through the wall of the tubular graft from an interior surface thereof, and positioning the fastener with one portion thereof extending through said vessel wall and another portion extending through said graft wall.

124. The method of claim 123 wherein the flexible member is selected to be a suture.

125. The method of claim 123 wherein all of the at least one flexible member and the piercing members are removed from the fastener. 124. The method of claim 80 wherein the flexible member is selected to be a suture.

126. Surgical apparatus comprising an elongated flexible tubular member.

127. The apparatus of claim 126 wherein said flexible tubular member is a suture.

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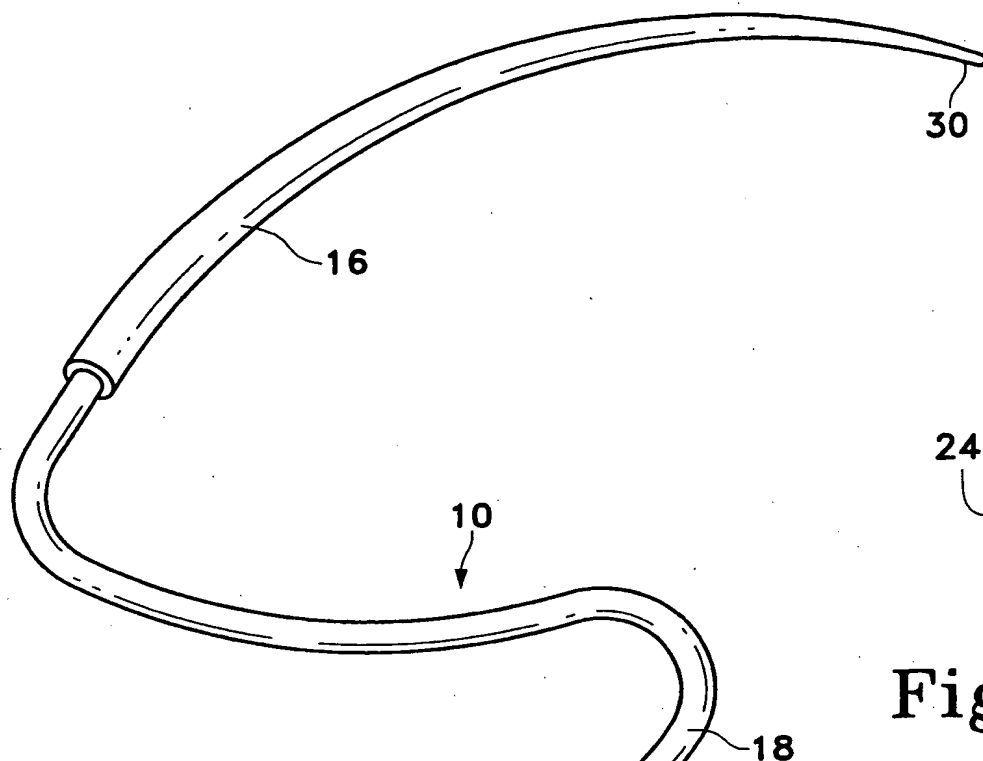


Fig. 1

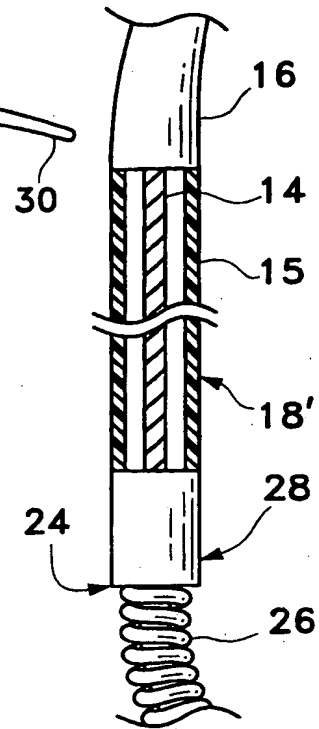
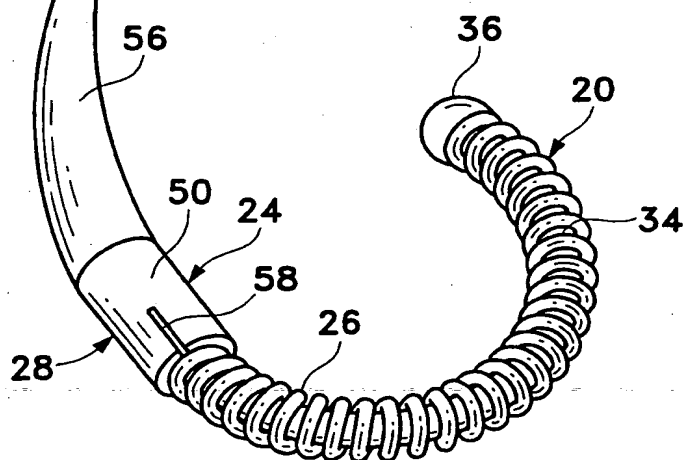


Fig. 1A

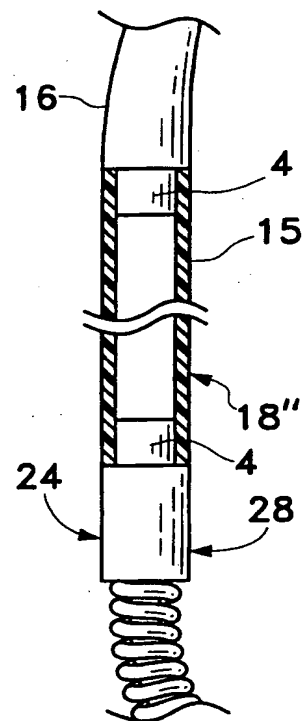


Fig. 1B

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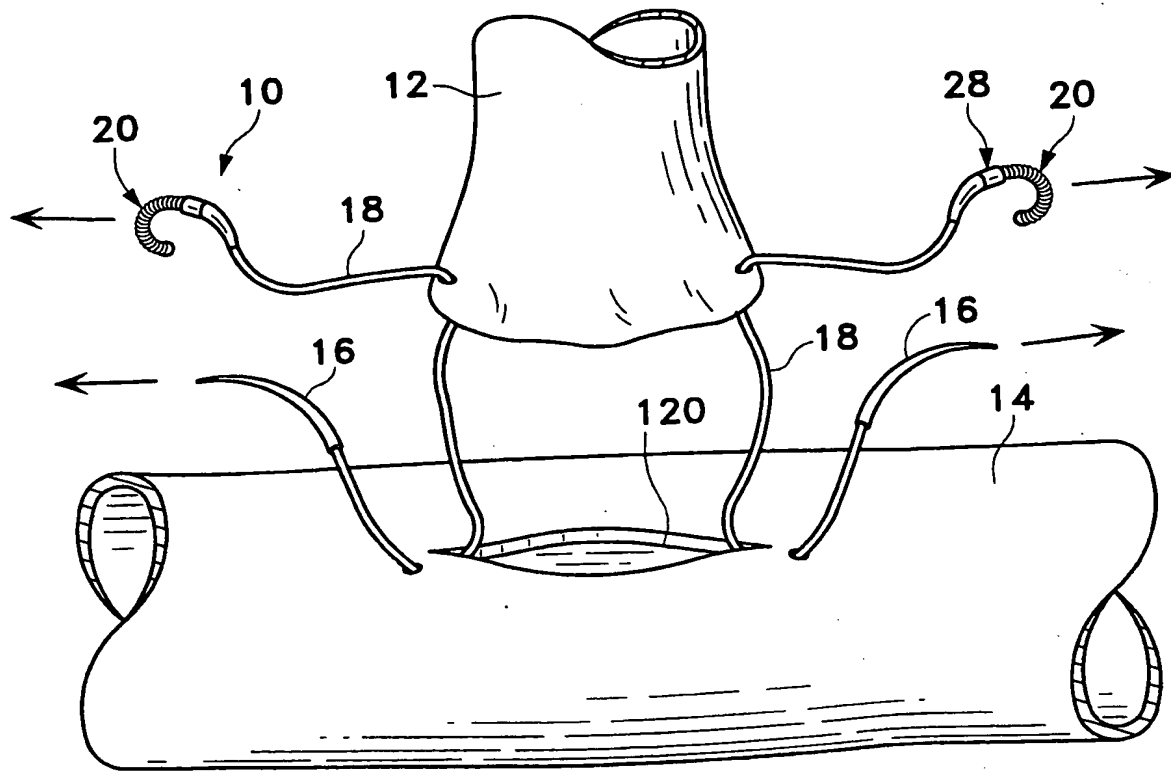


FIG. 2A

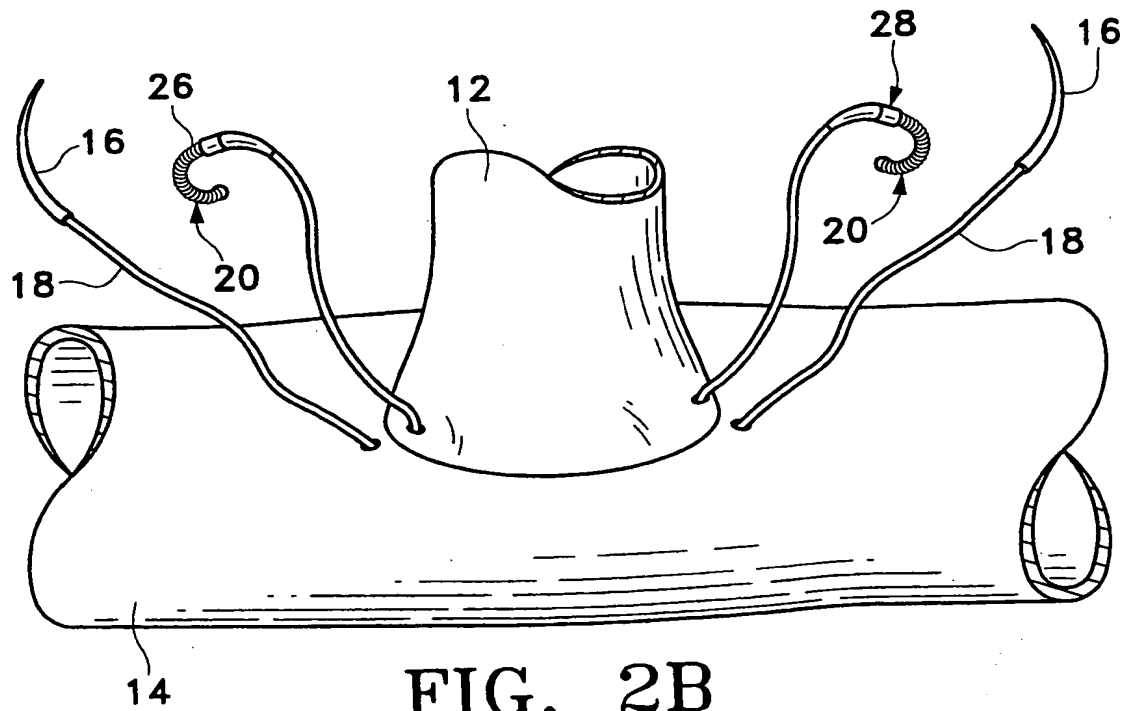


FIG. 2B

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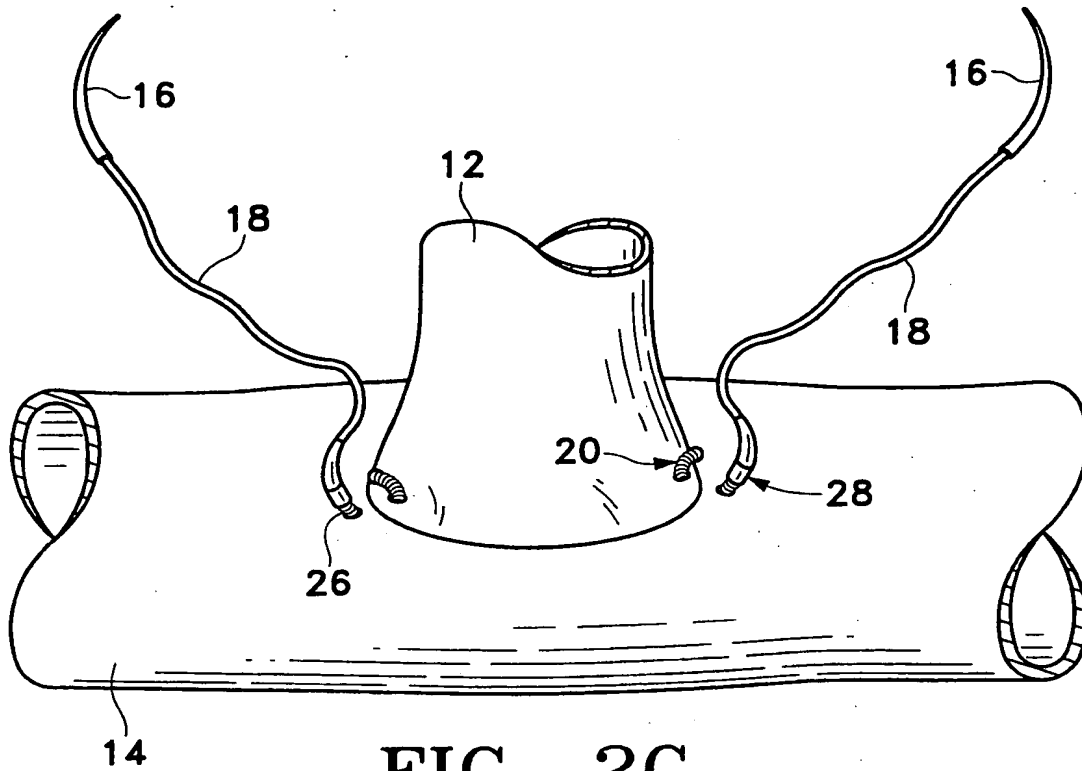


FIG. 2C

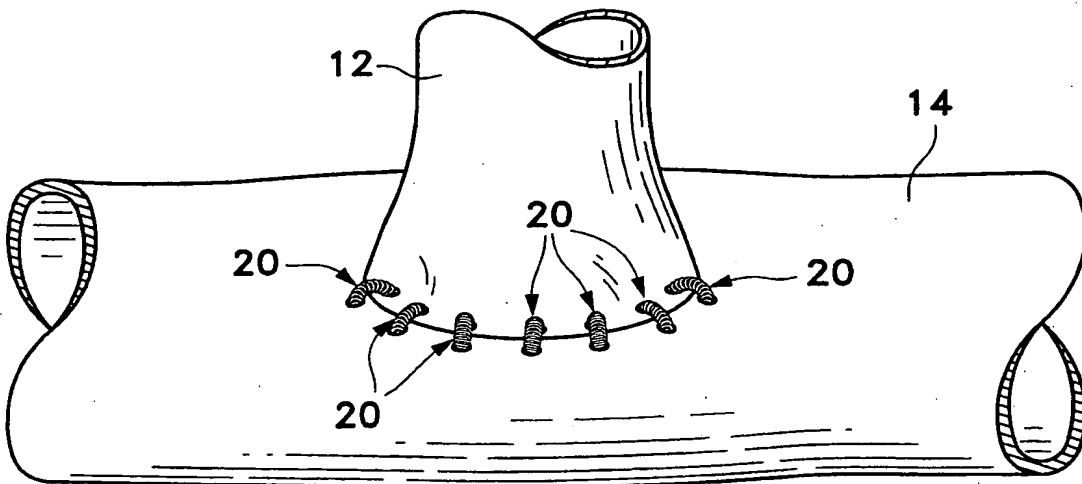


FIG. 2D

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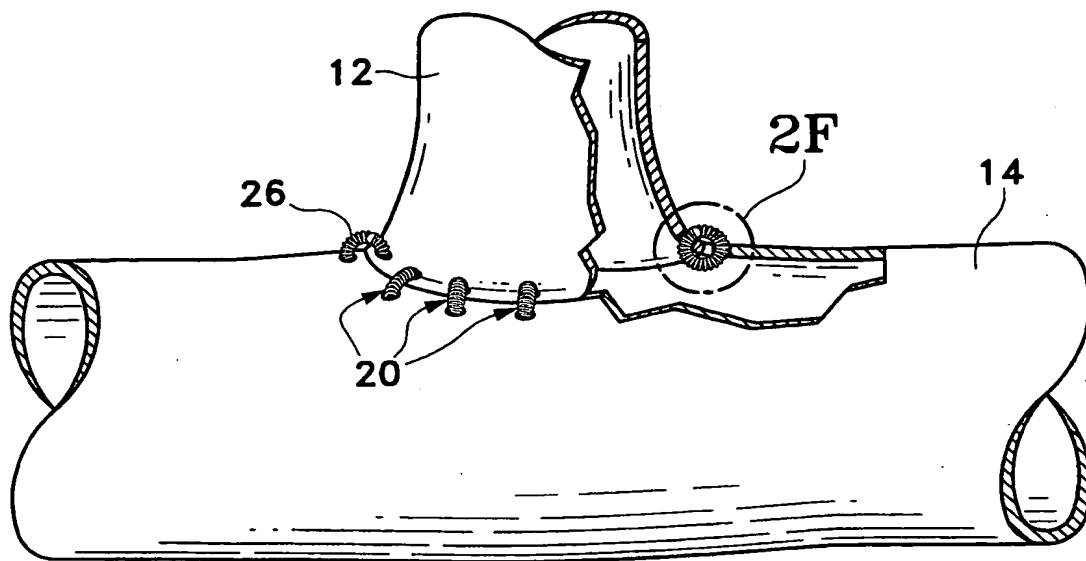


Fig. 2E

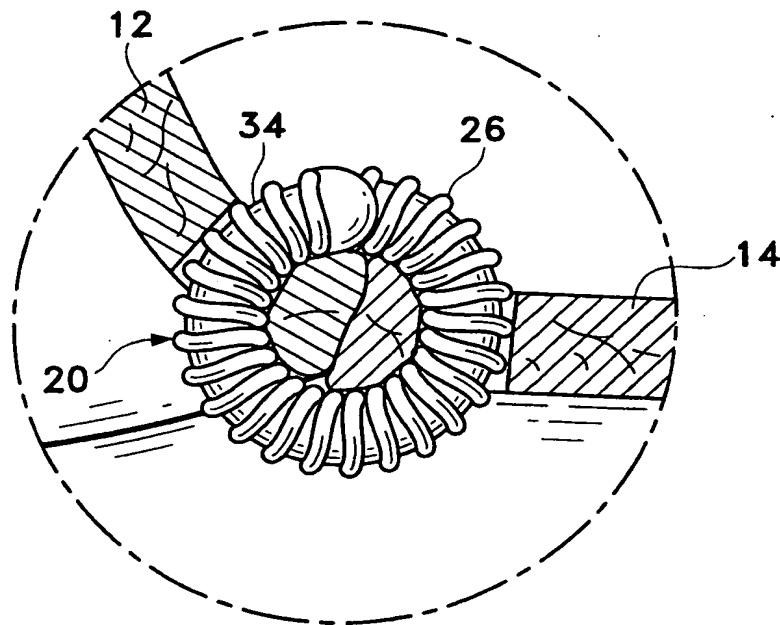


Fig. 2F

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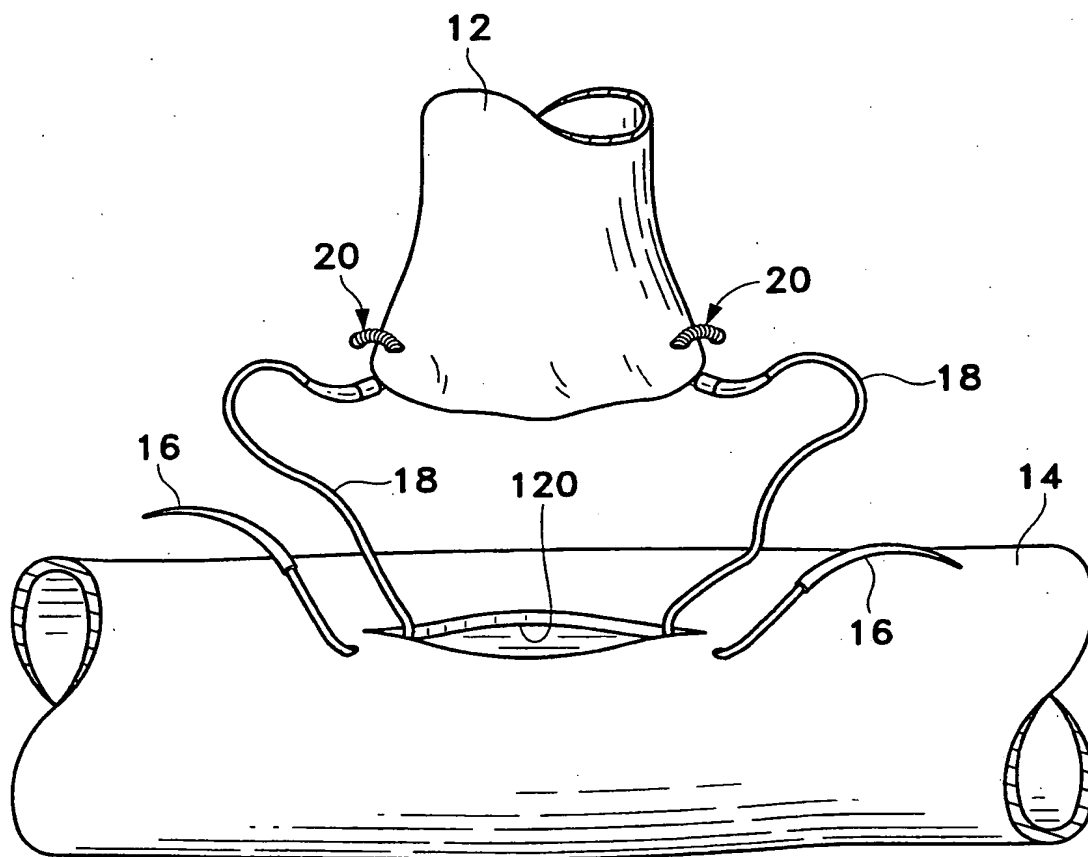


FIG. 2G

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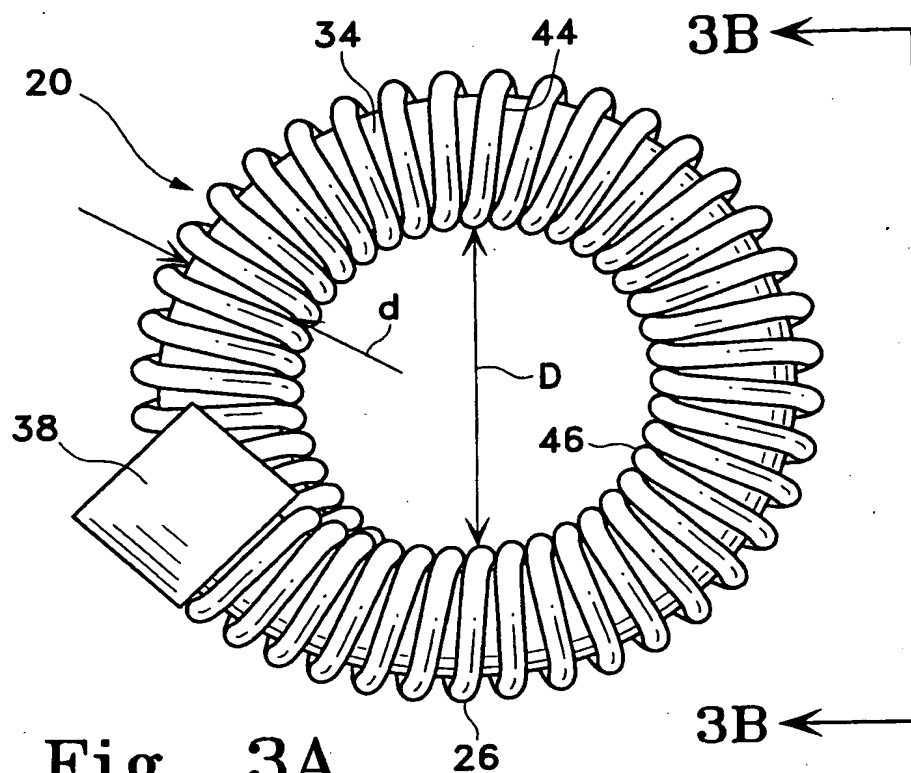


Fig. 3A

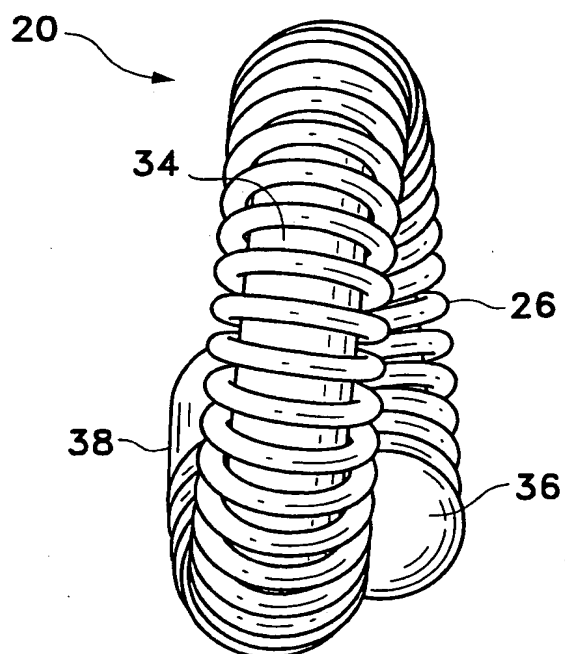
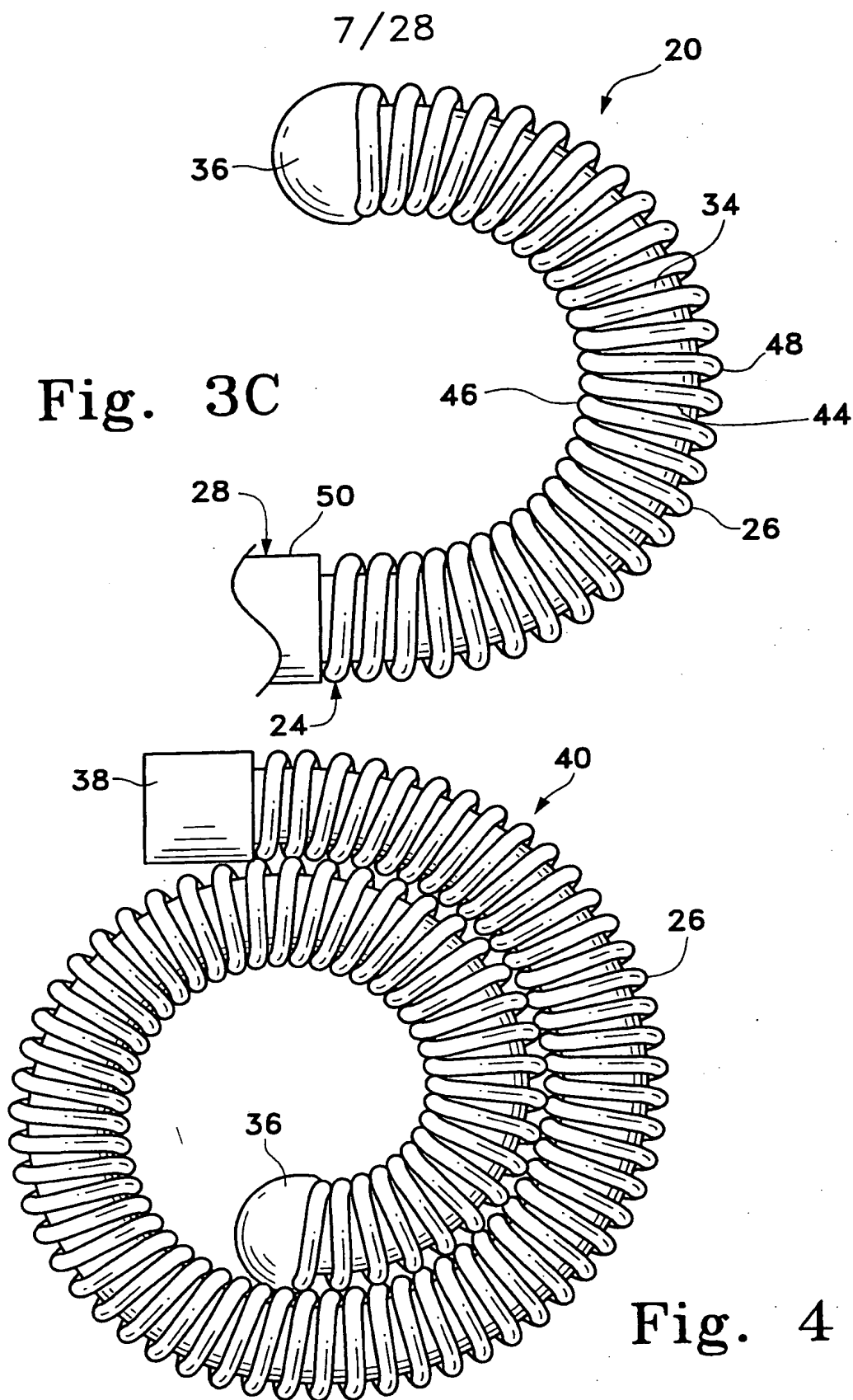


Fig. 3B

Fig. 3C



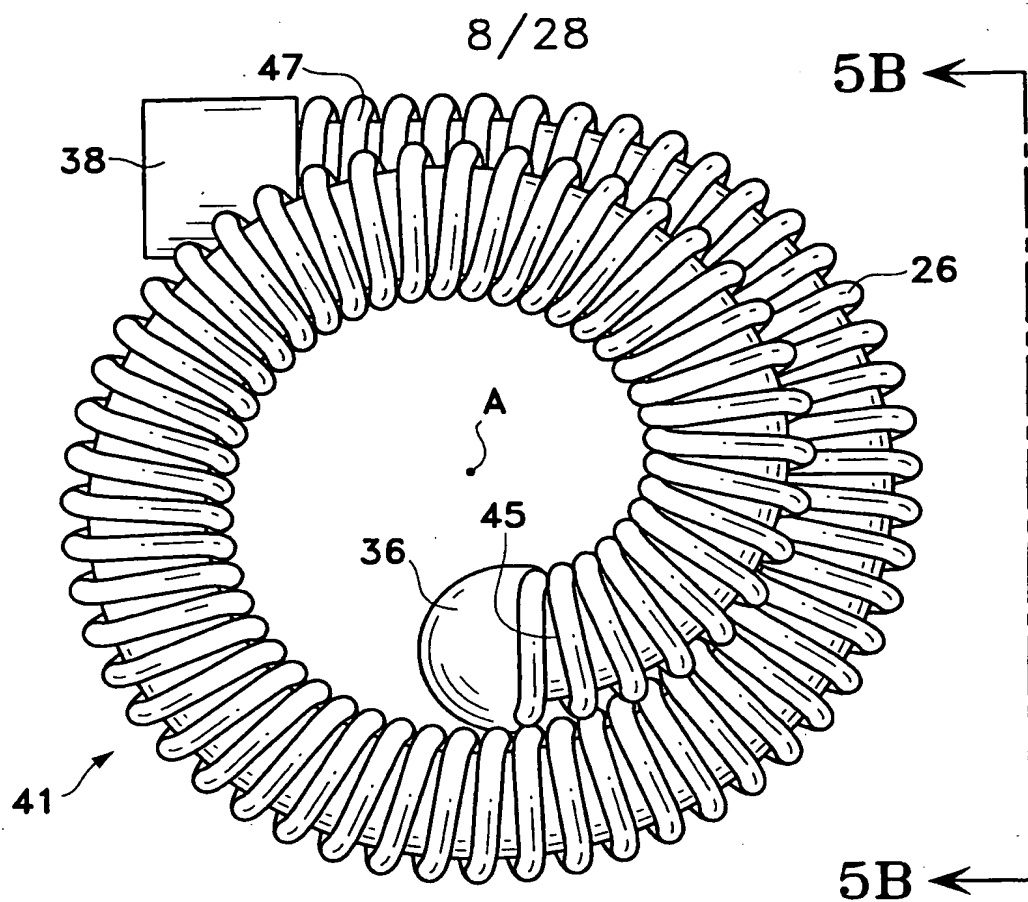


Fig. 5A

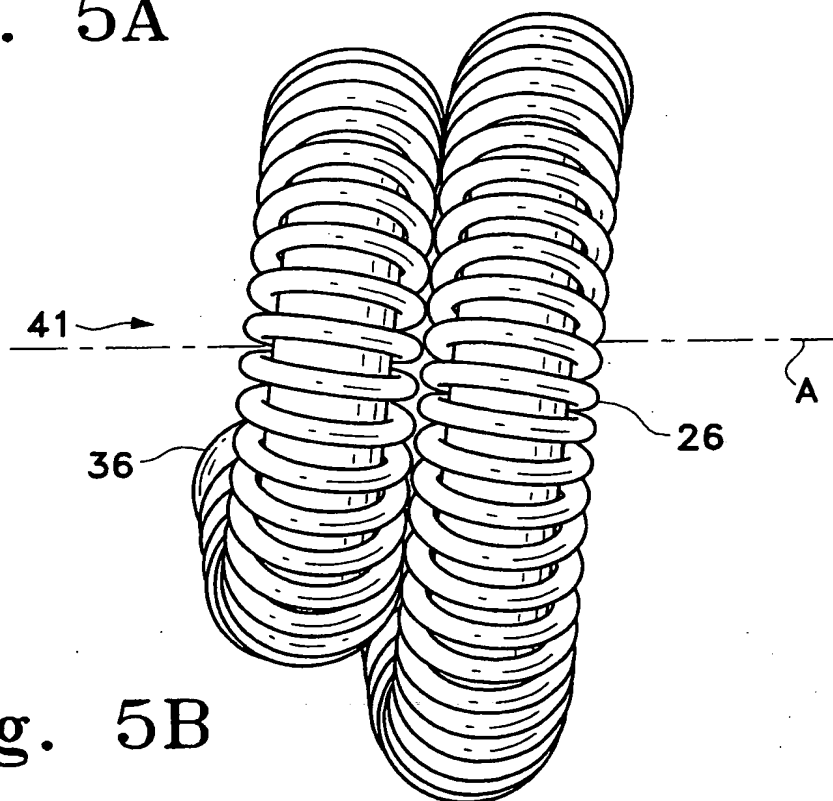
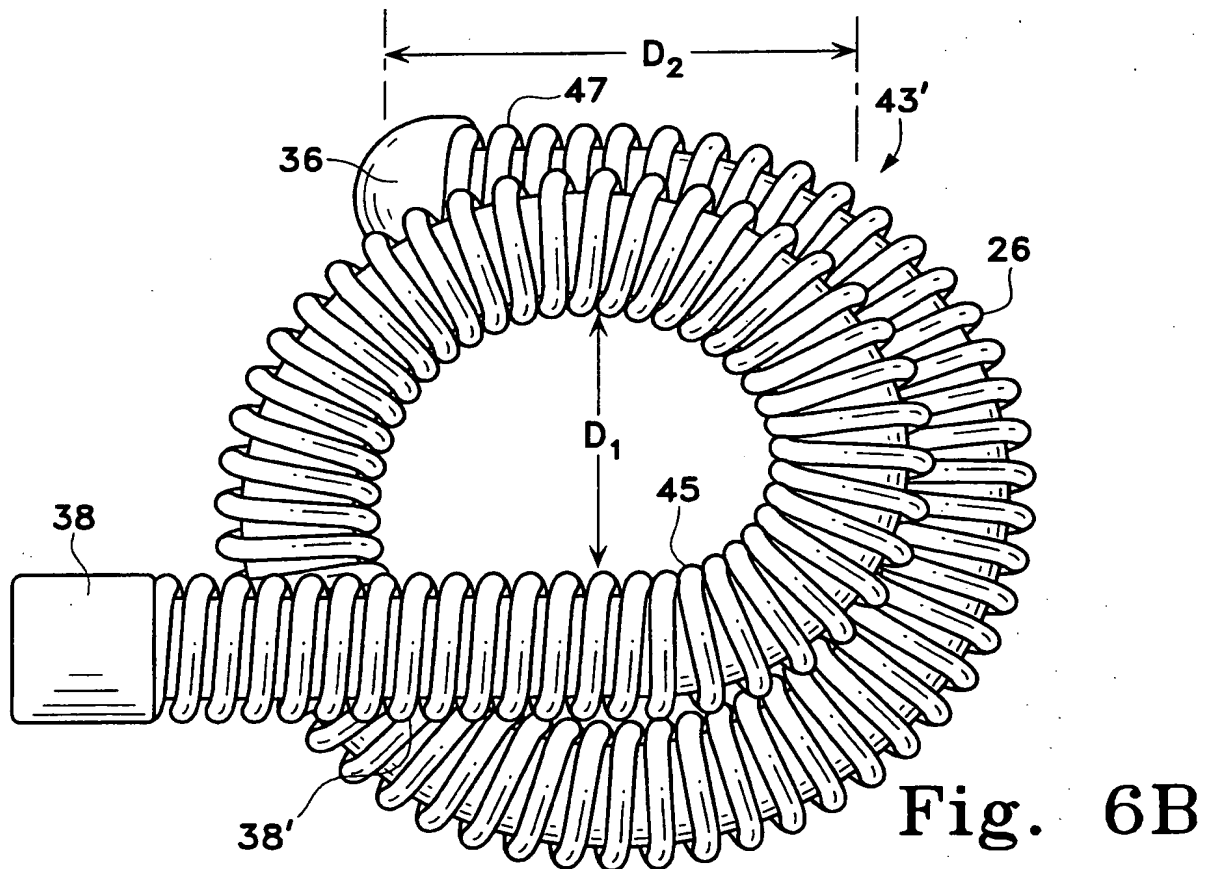
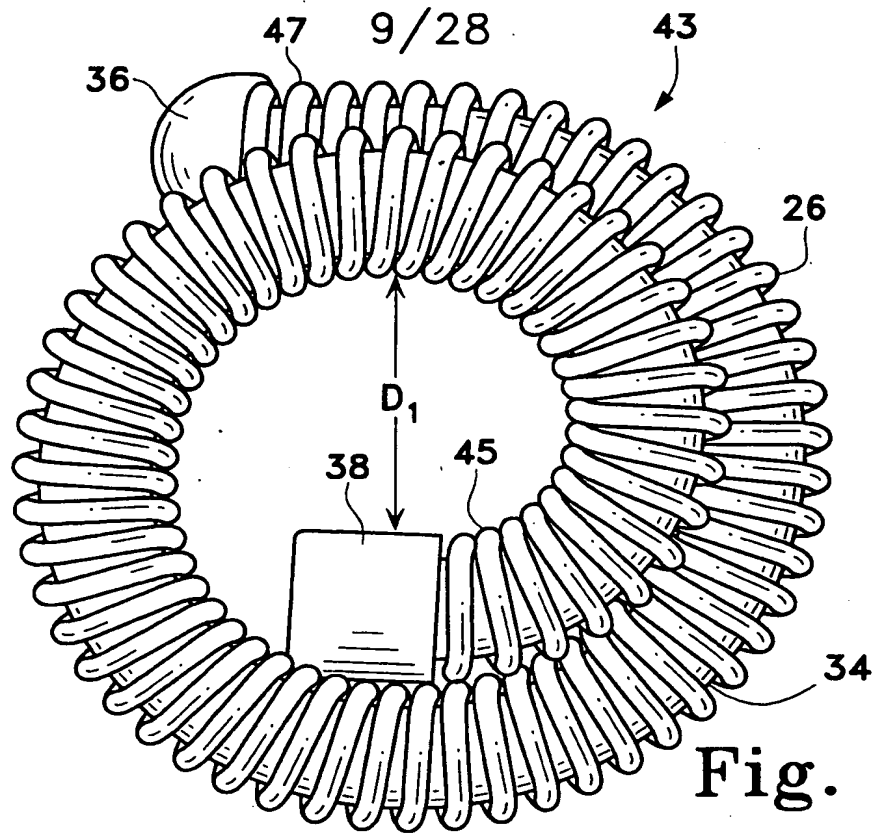


Fig. 5B



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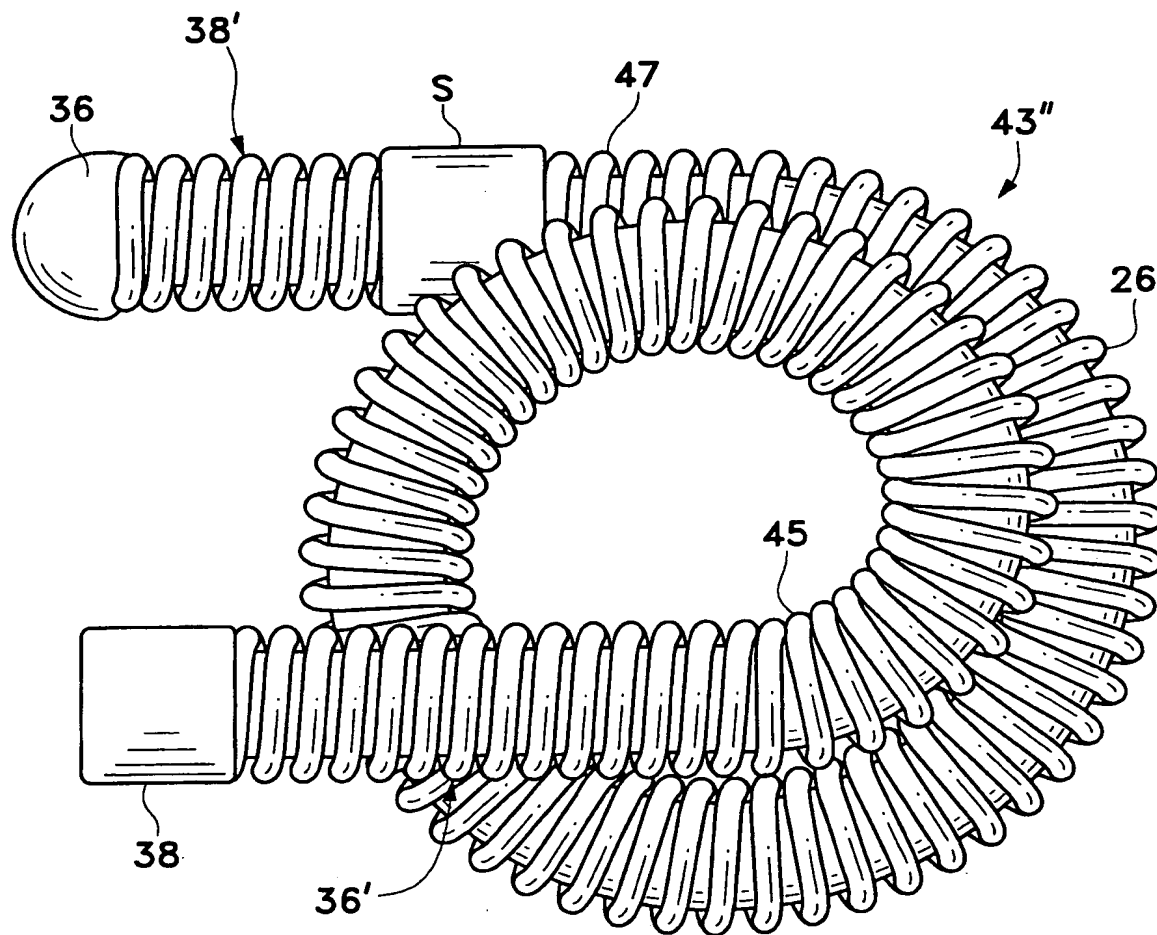


Fig. 6C

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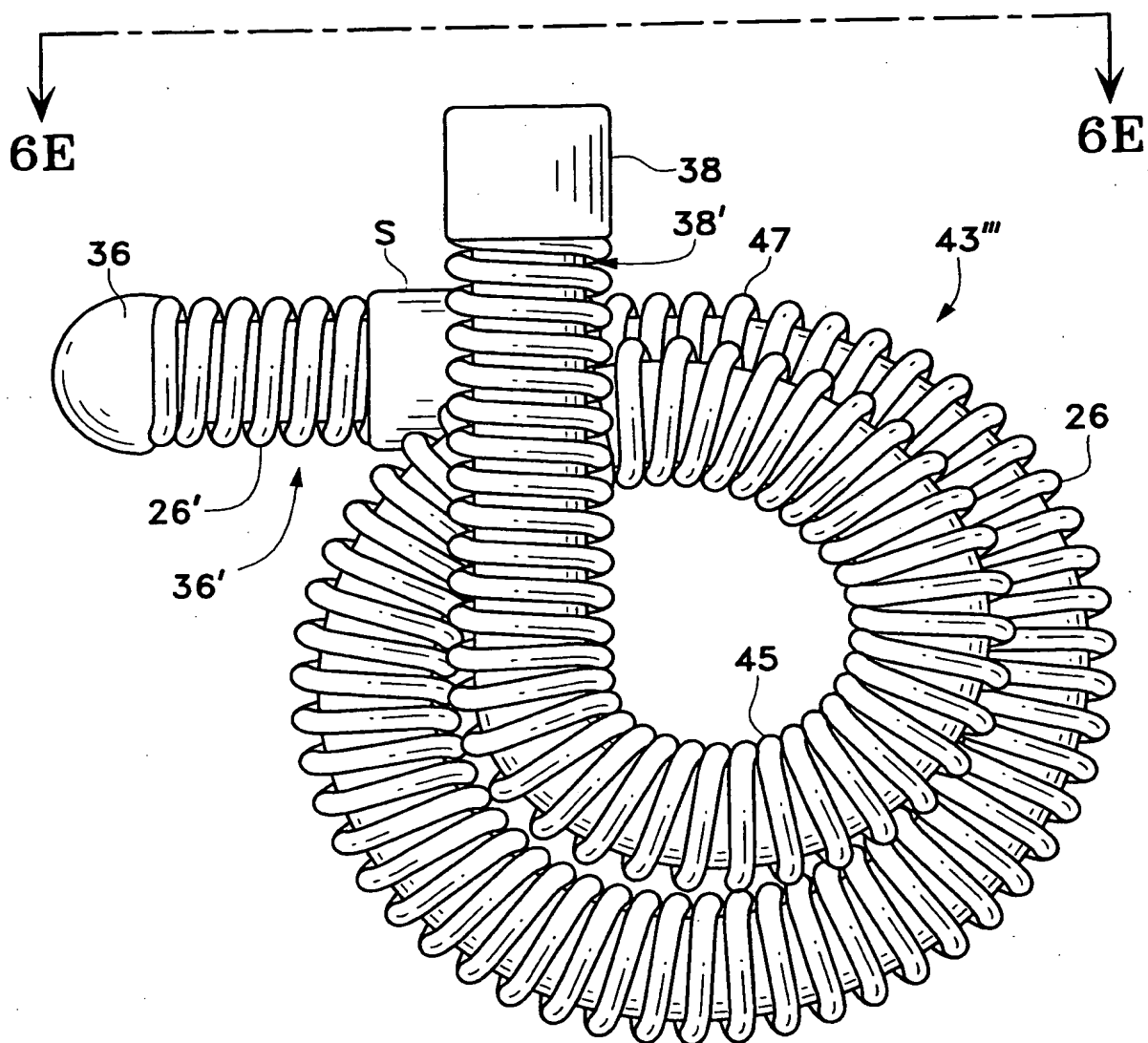


Fig. 6D

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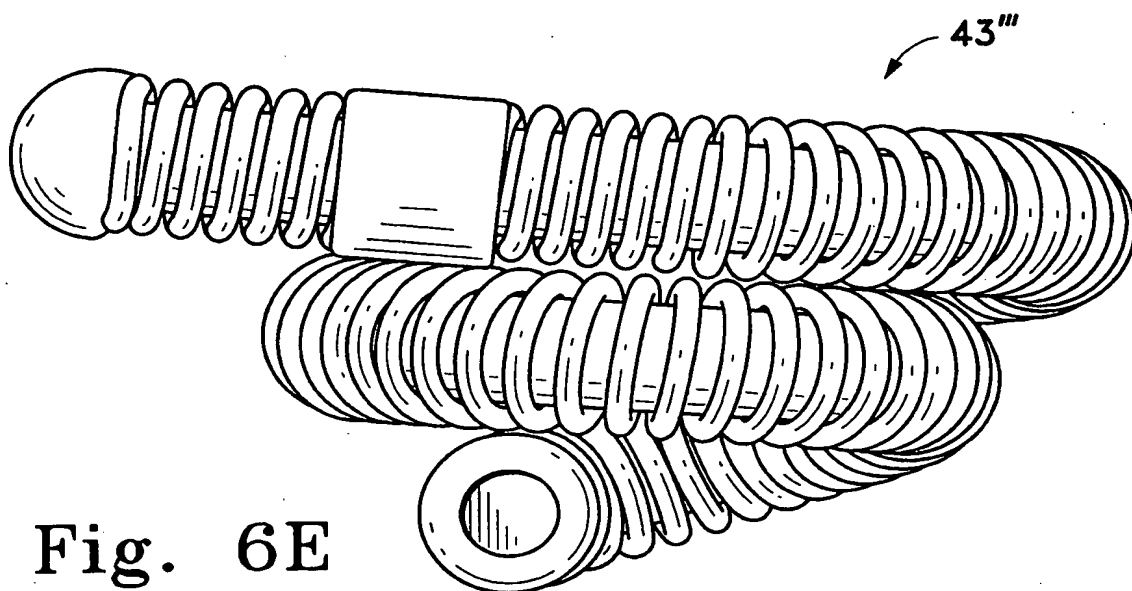


Fig. 6E

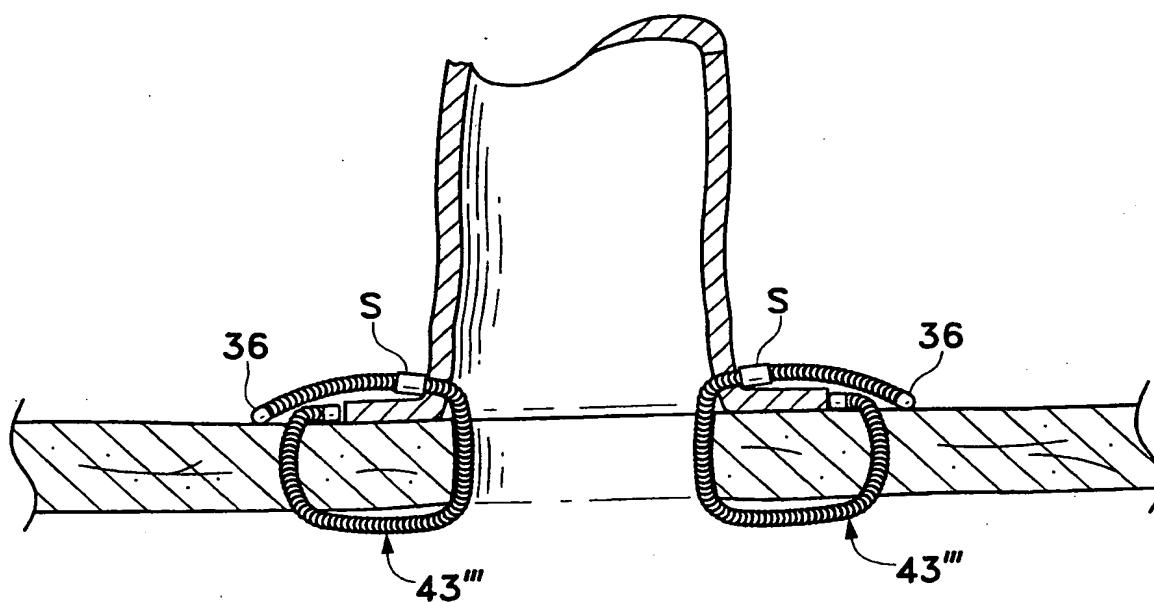
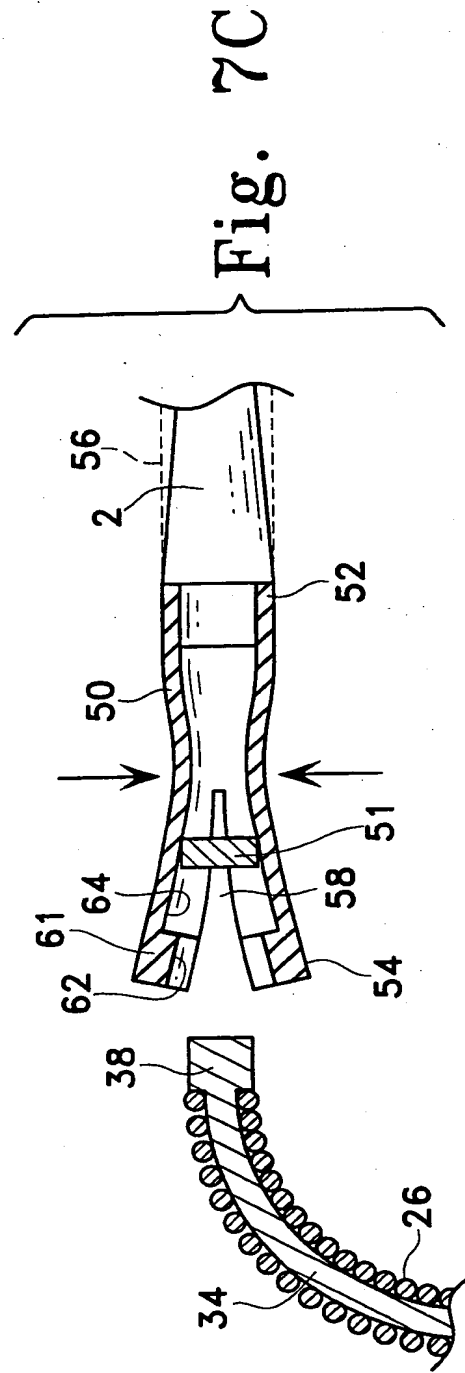
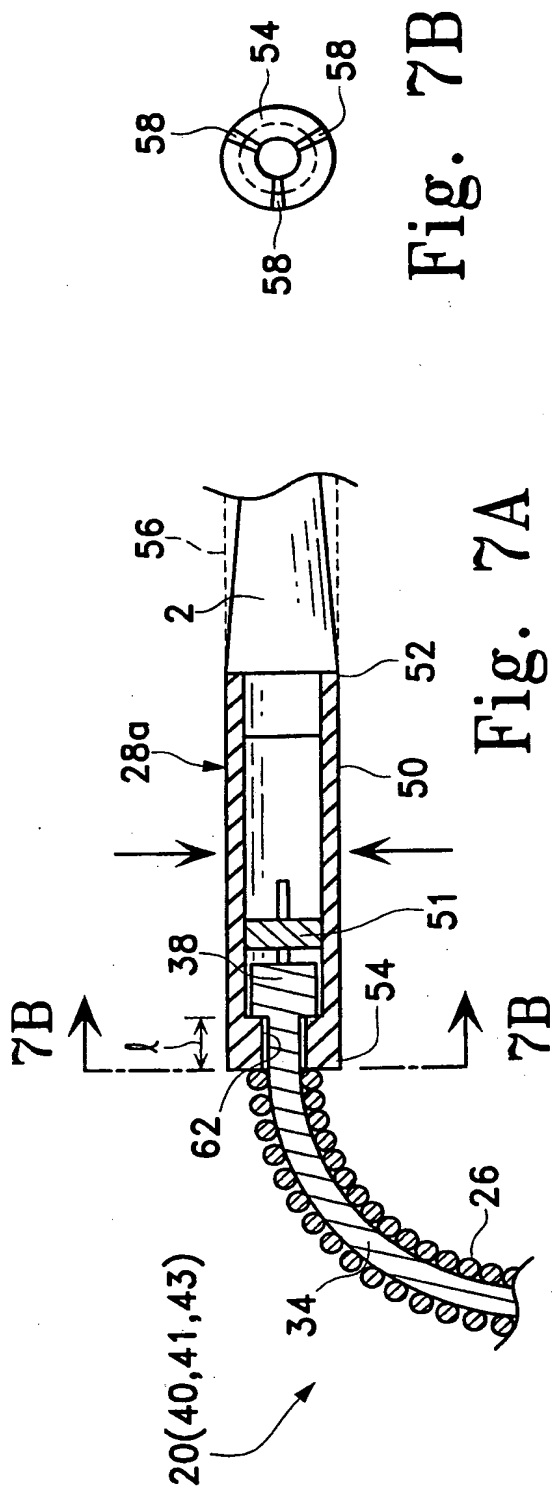


Fig. 6F



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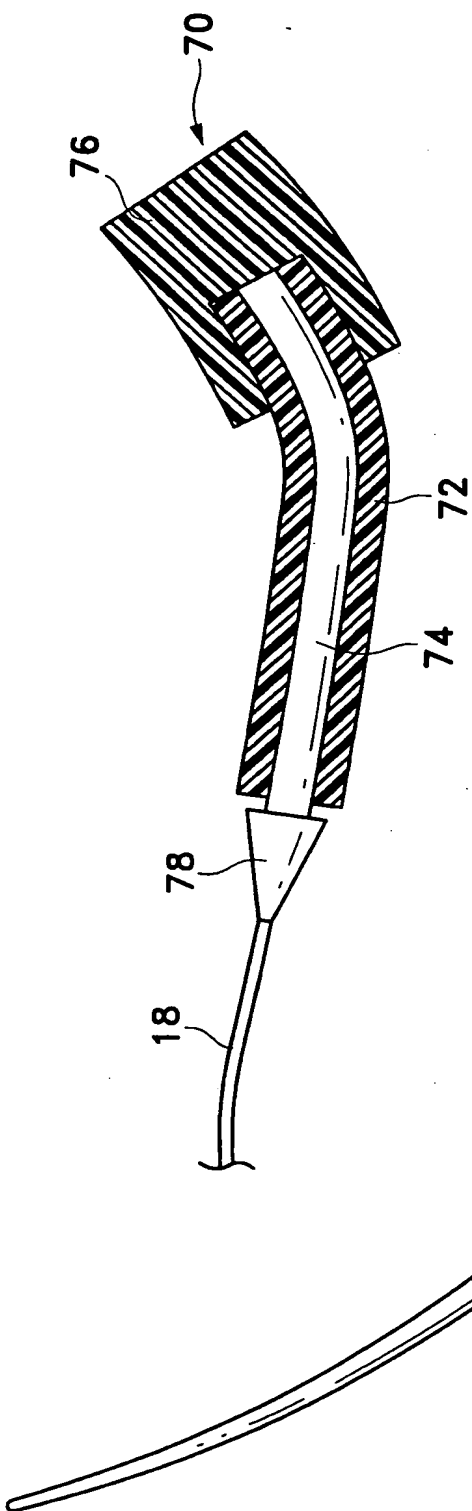


Fig. 8

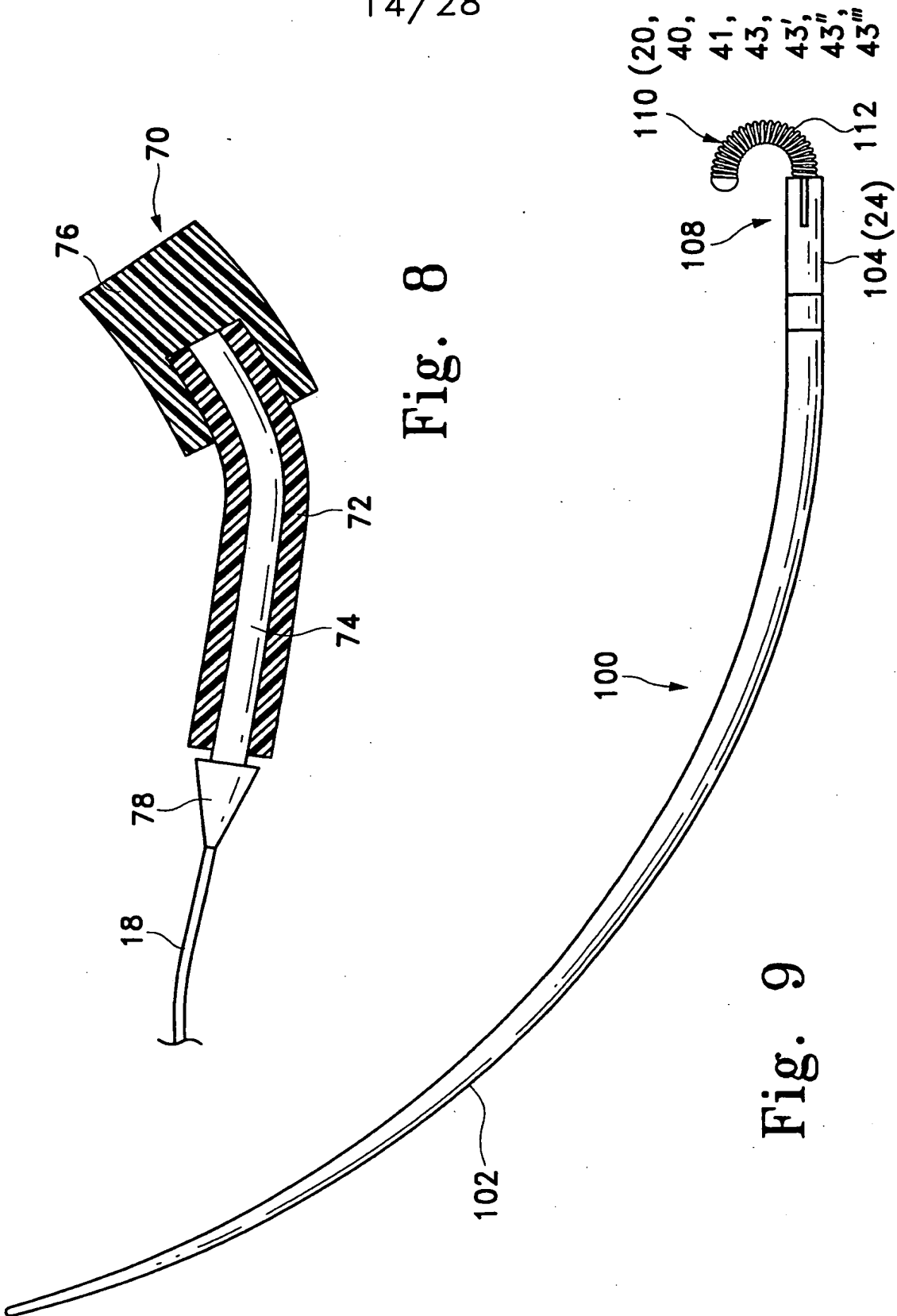


Fig. 9

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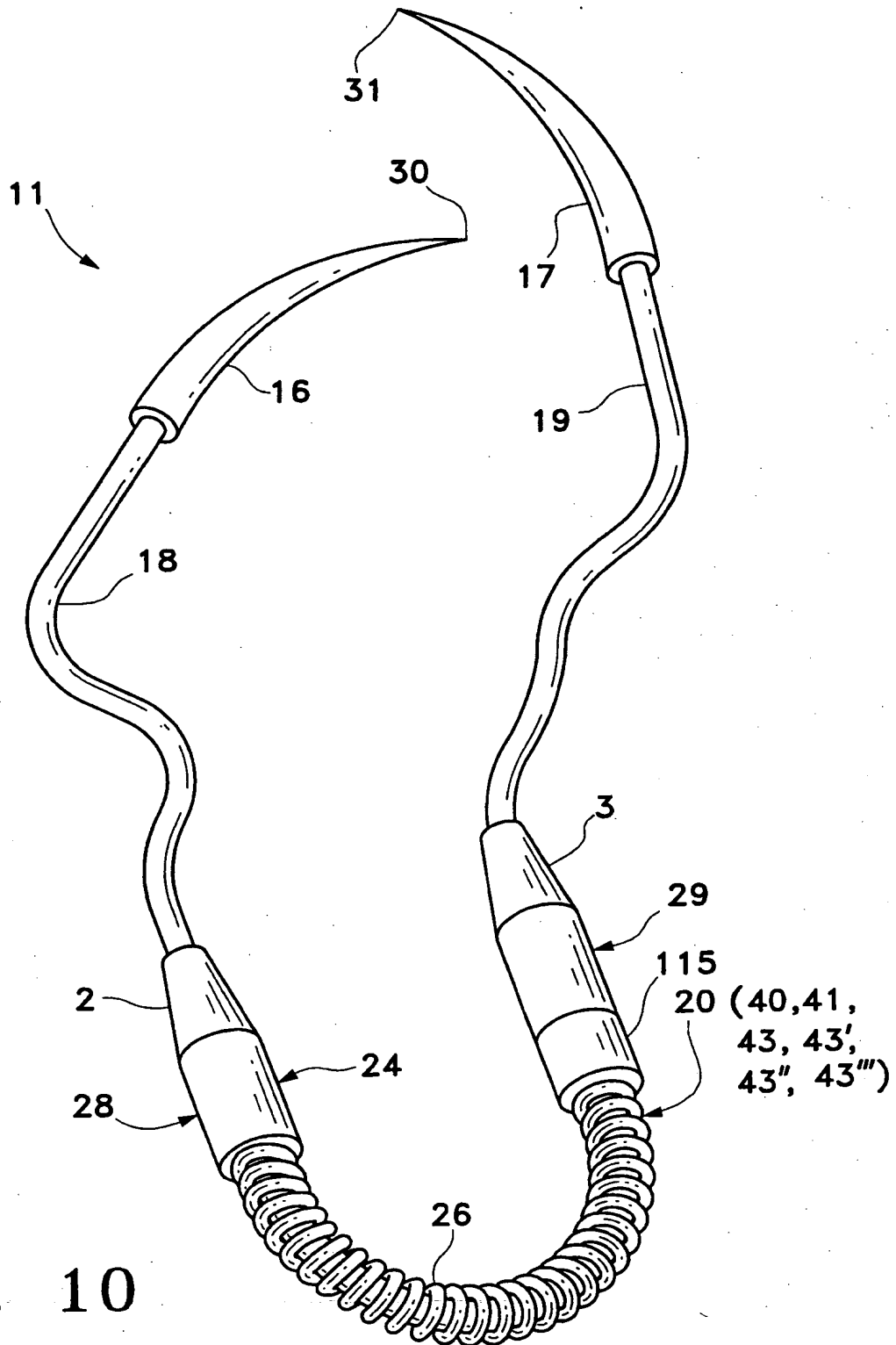
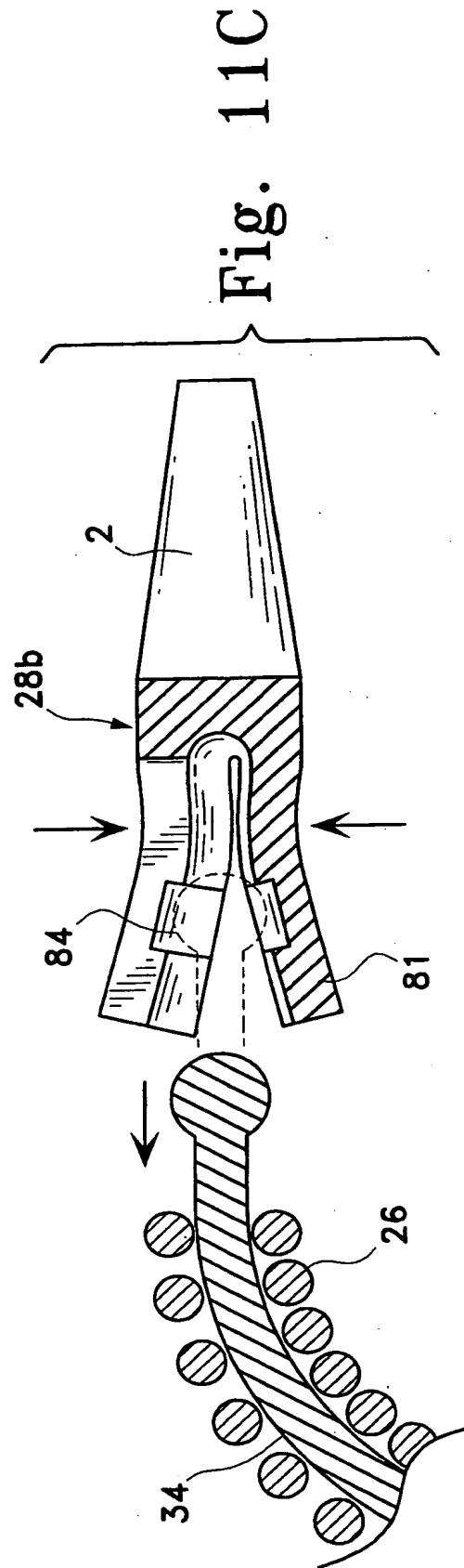
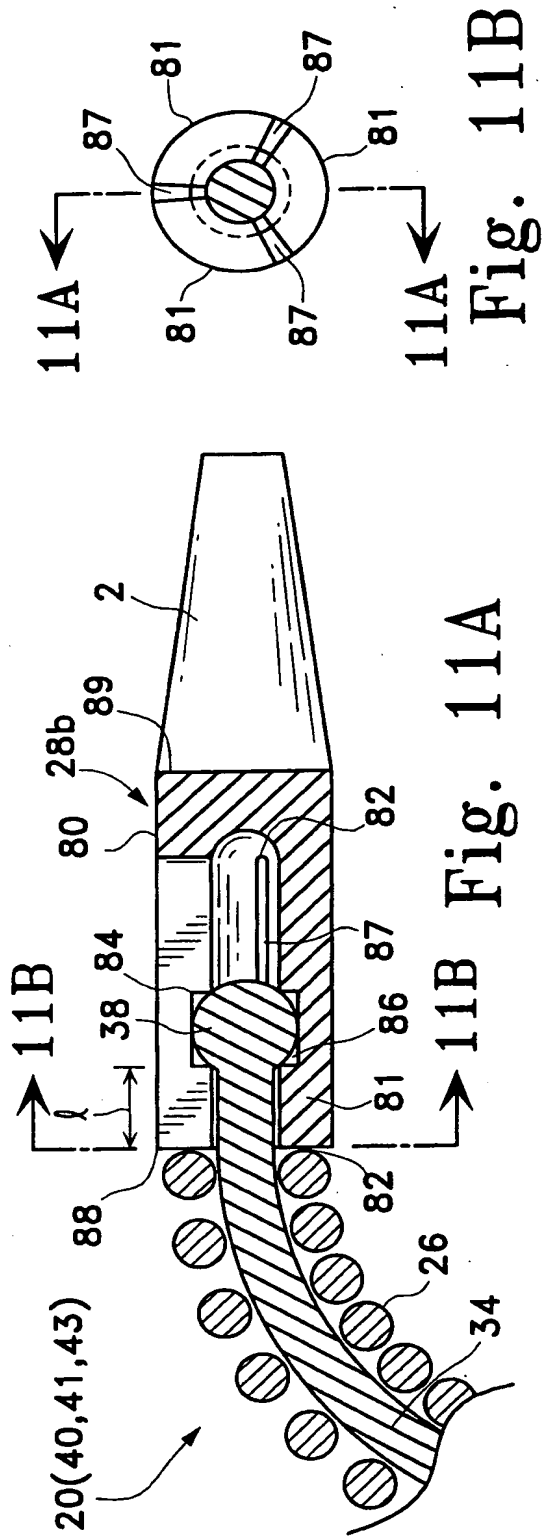


Fig. 10

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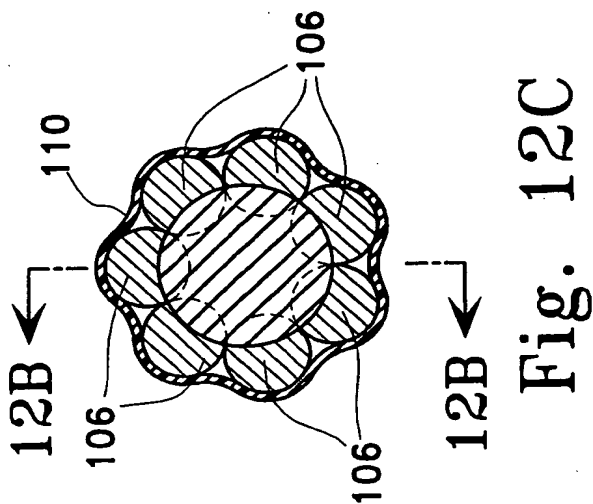
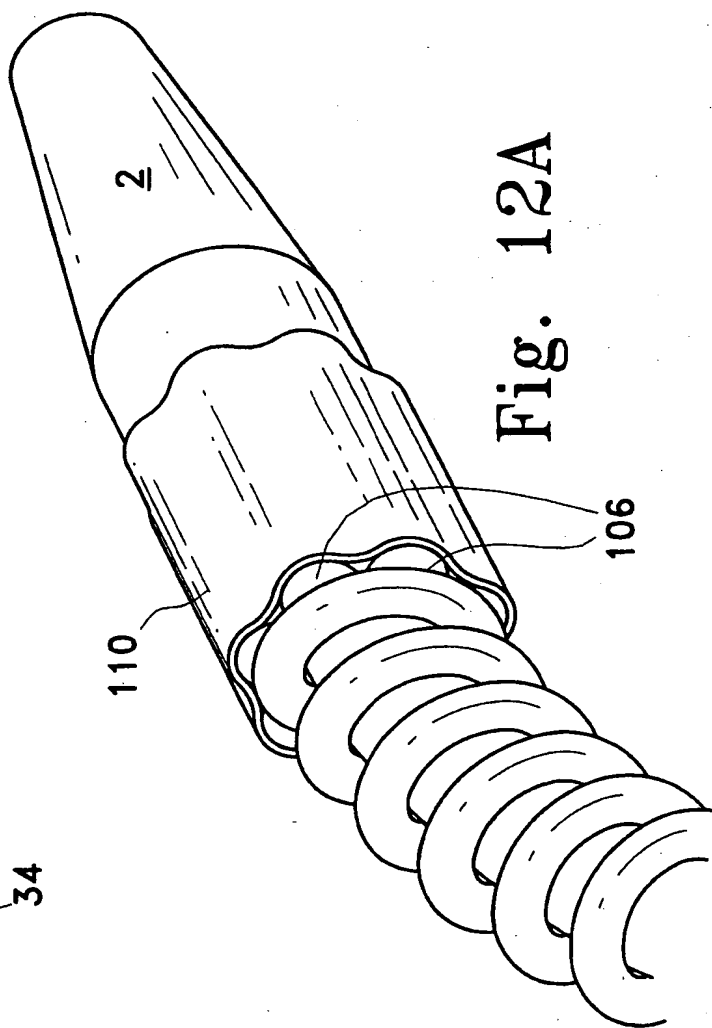
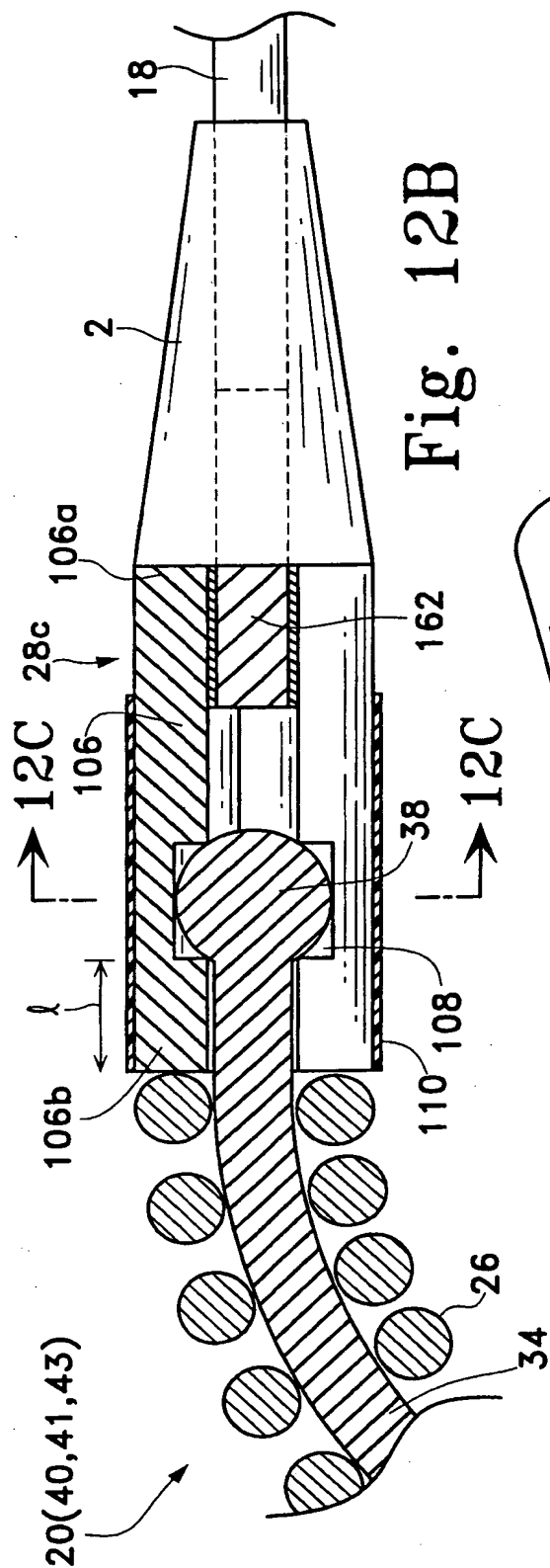


Fig. 12D

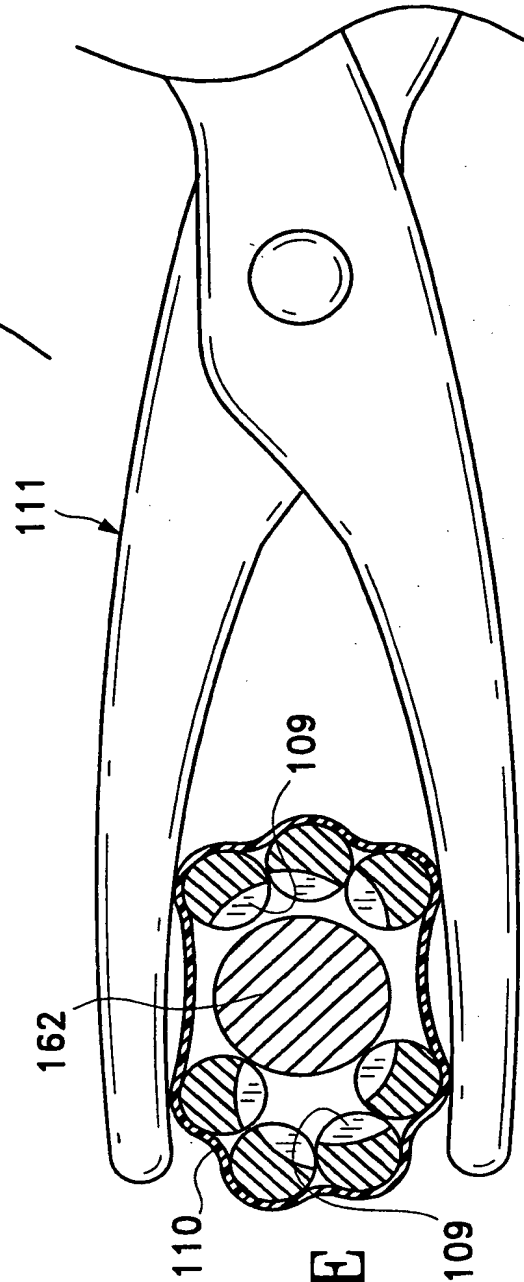
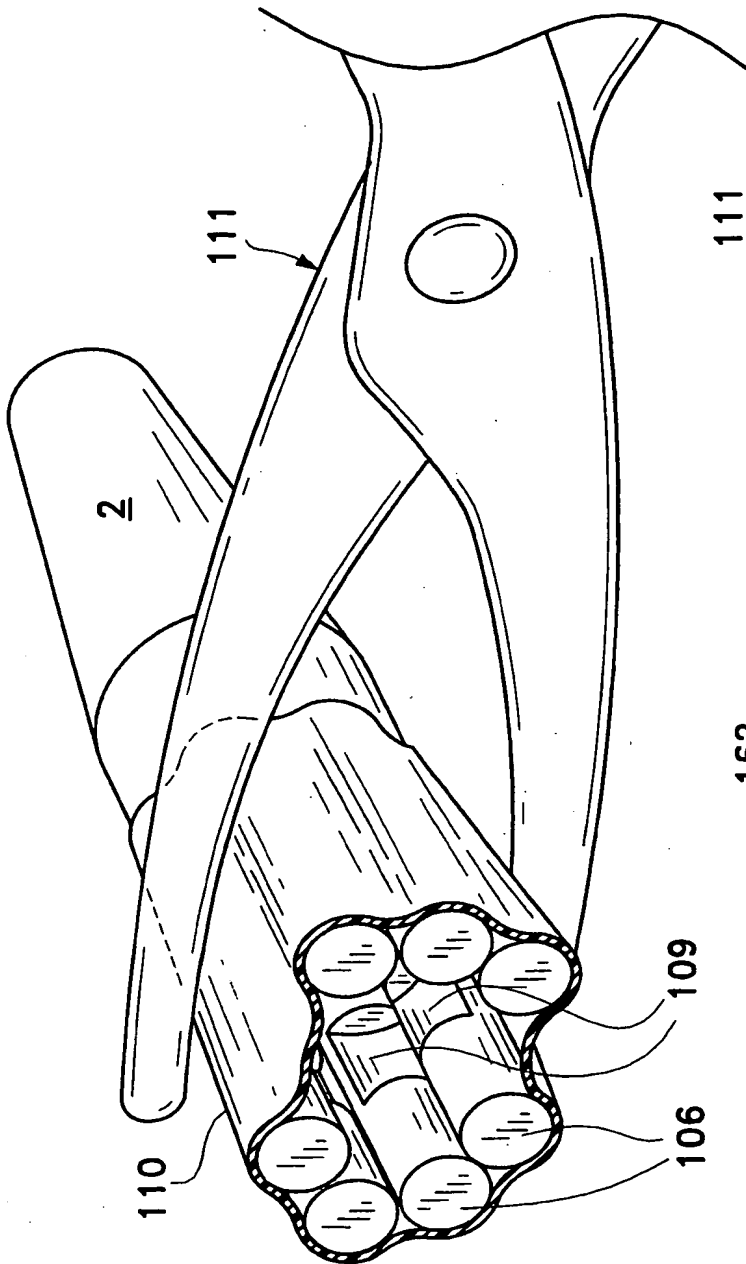


Fig. 12E

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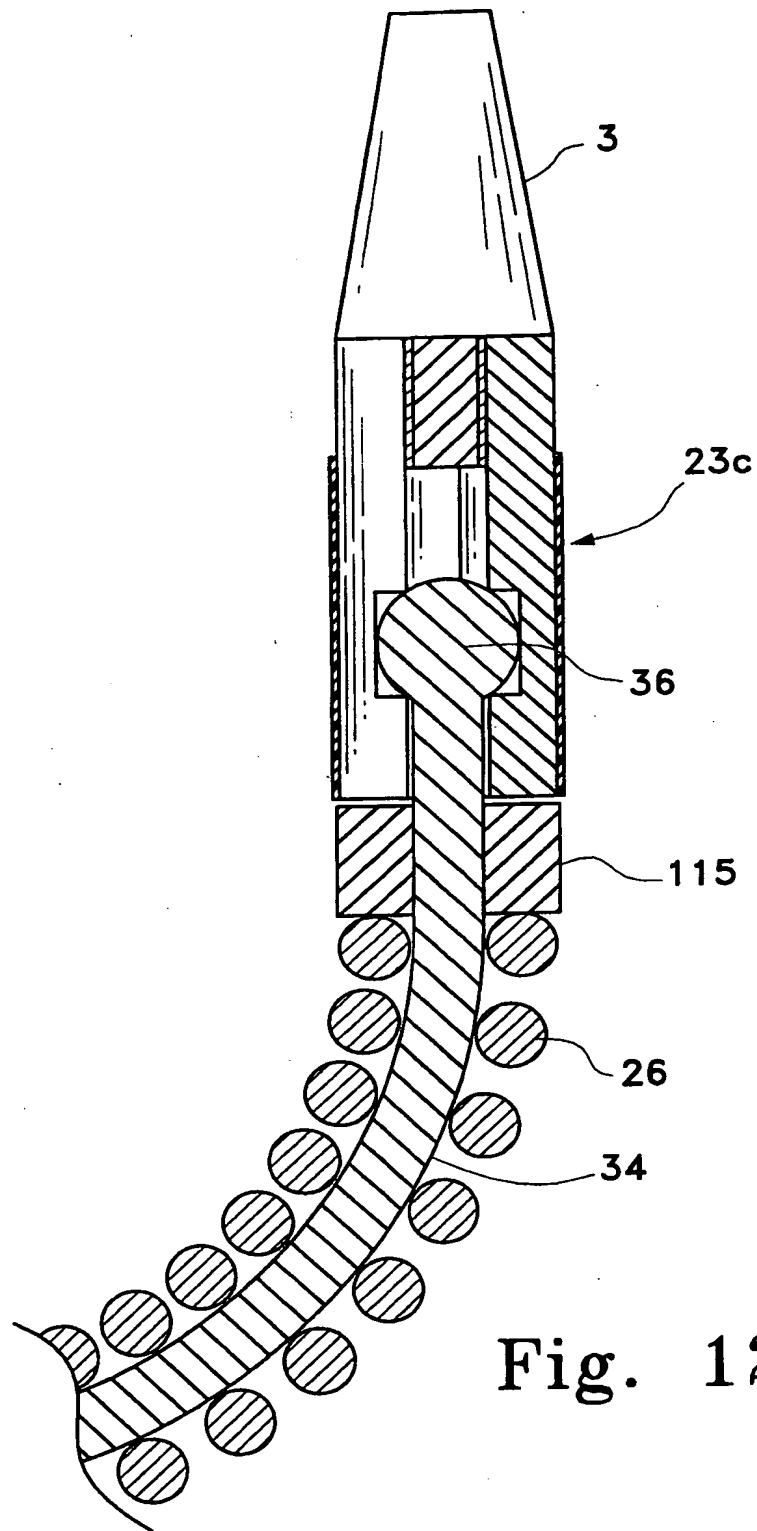


Fig. 12F

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Fig. 13A

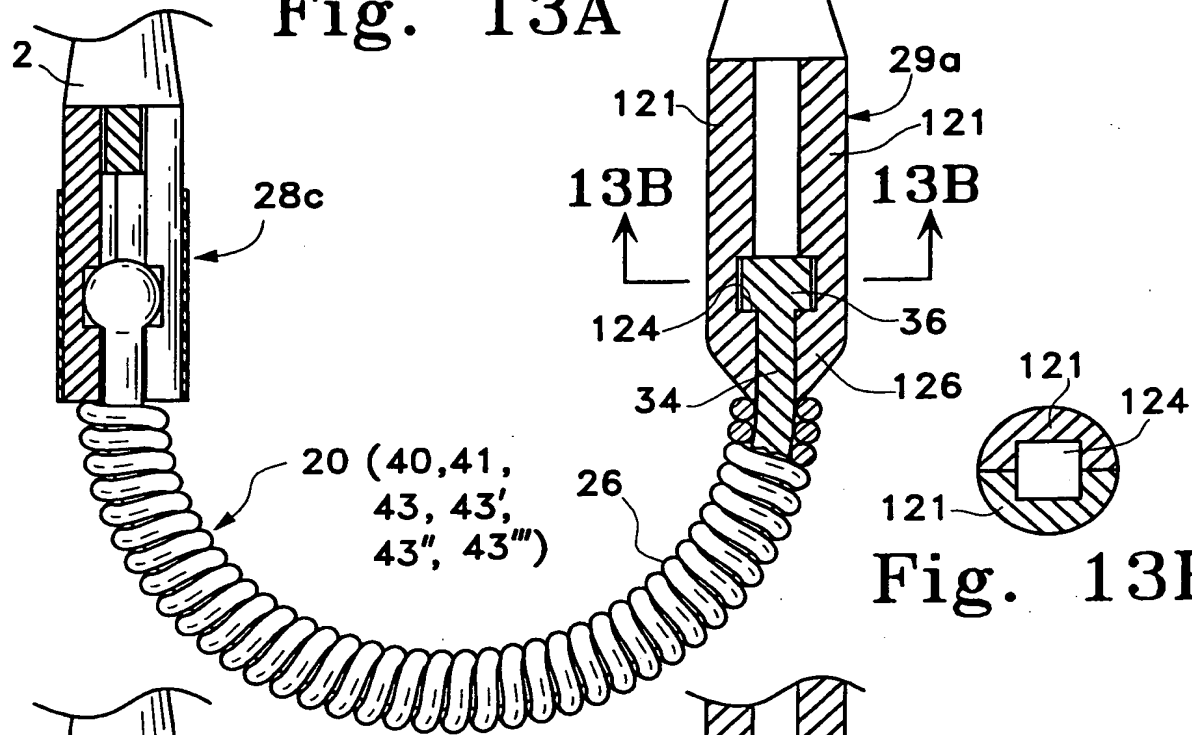


Fig. 13B

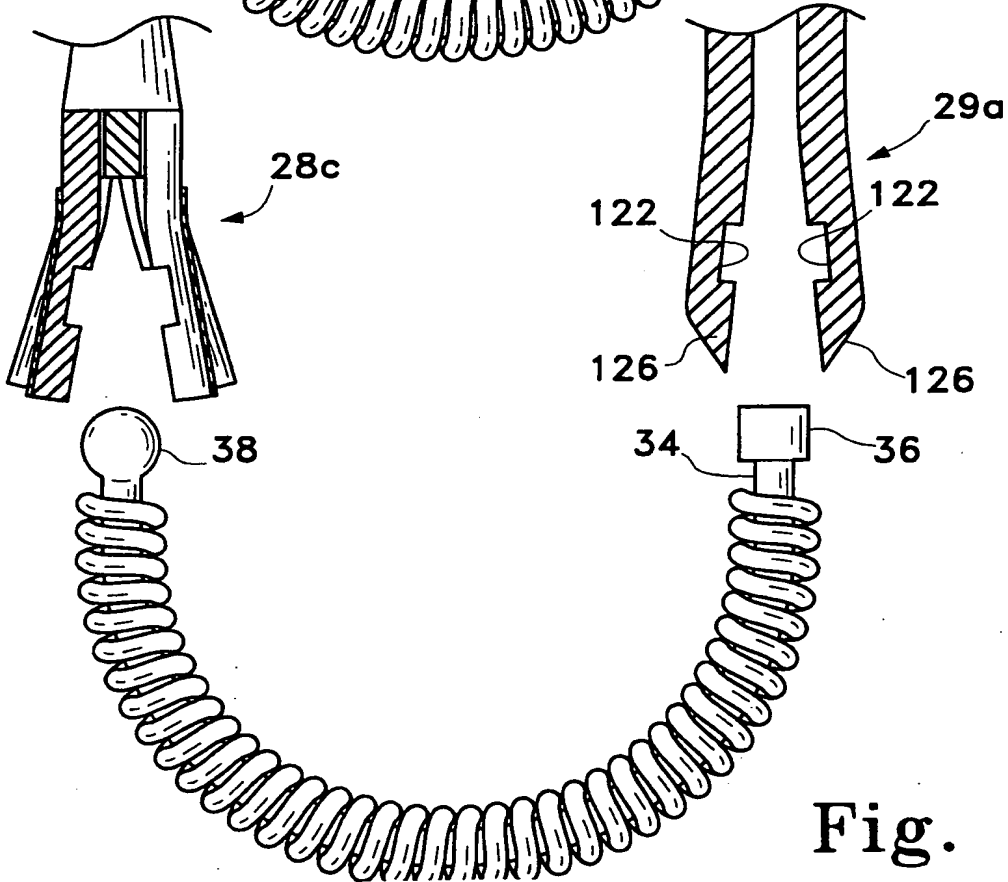
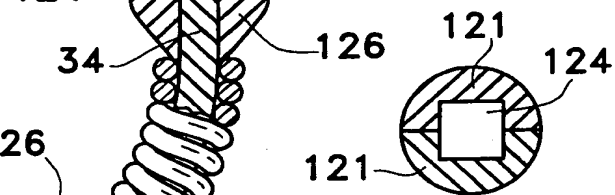


Fig. 13C

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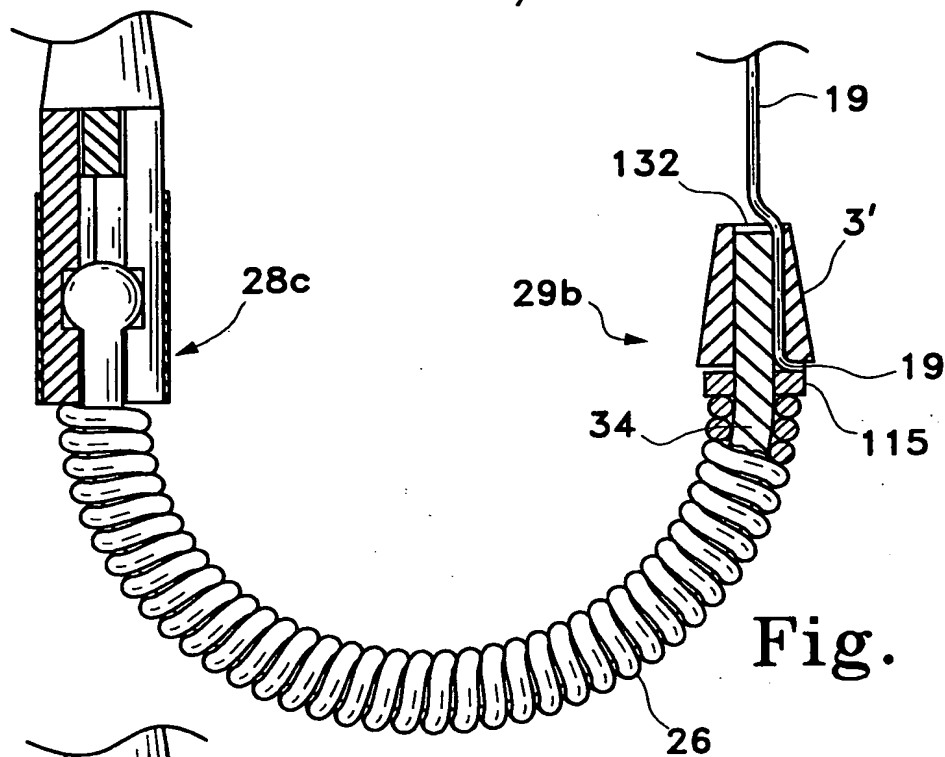


Fig. 13D

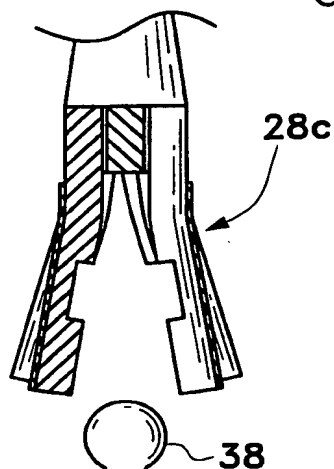


Fig. 13E

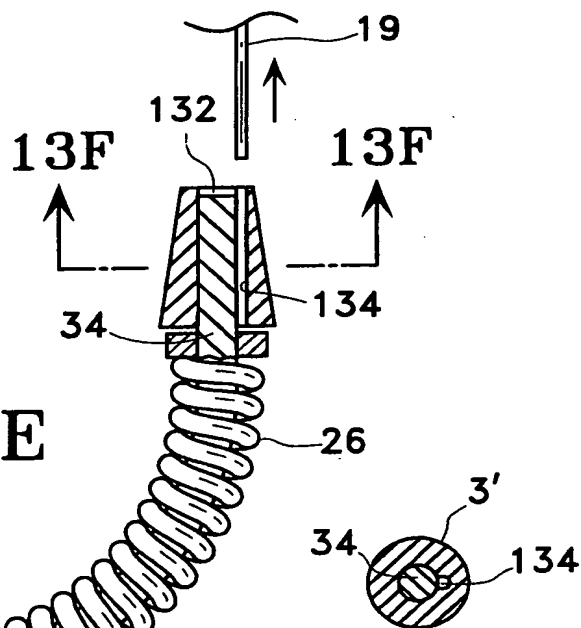


Fig. 13F

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Fig. 14A

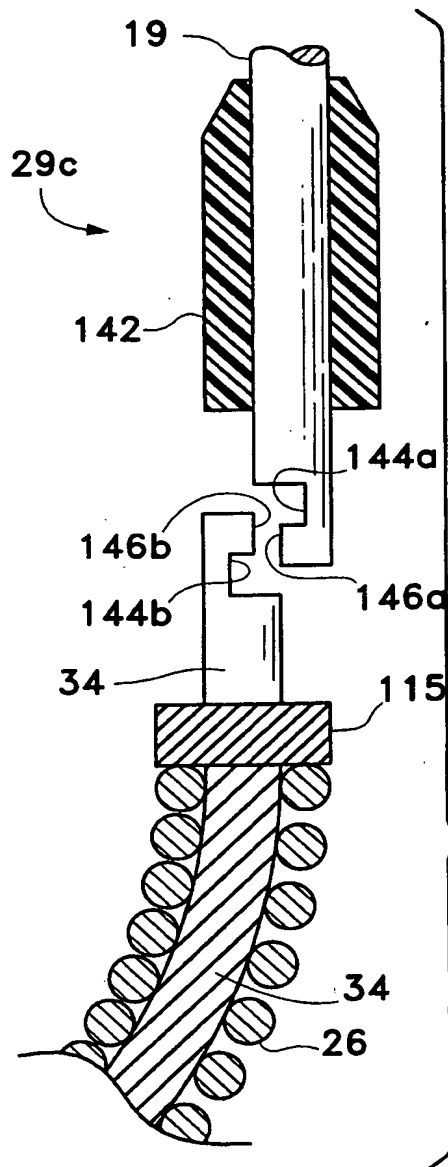
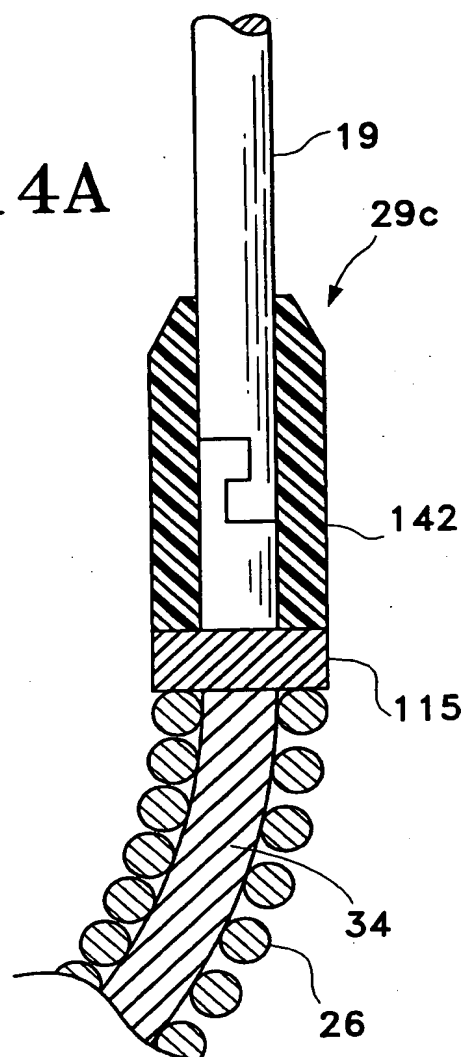


Fig. 14B

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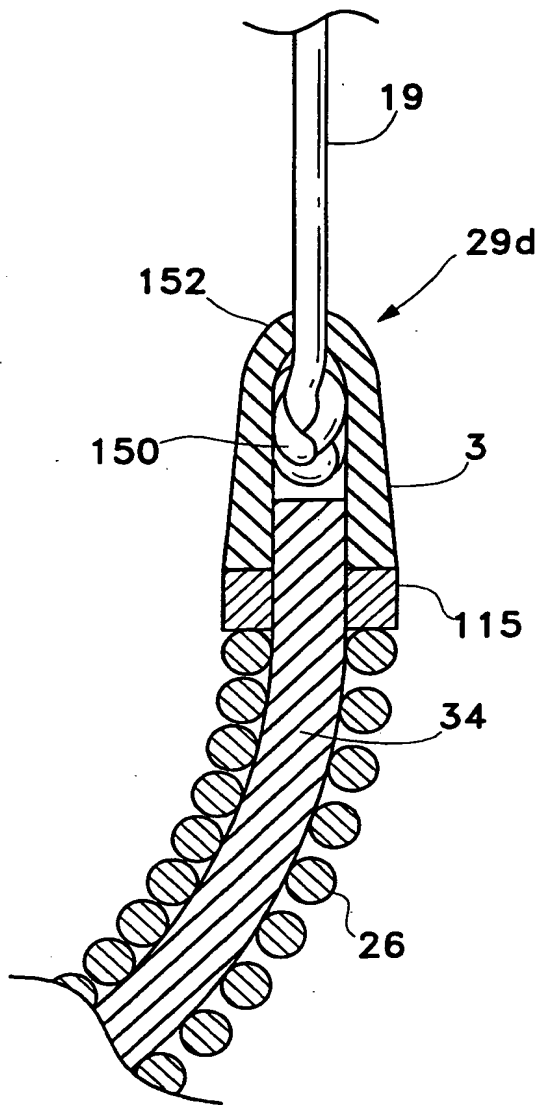


Fig. 15A

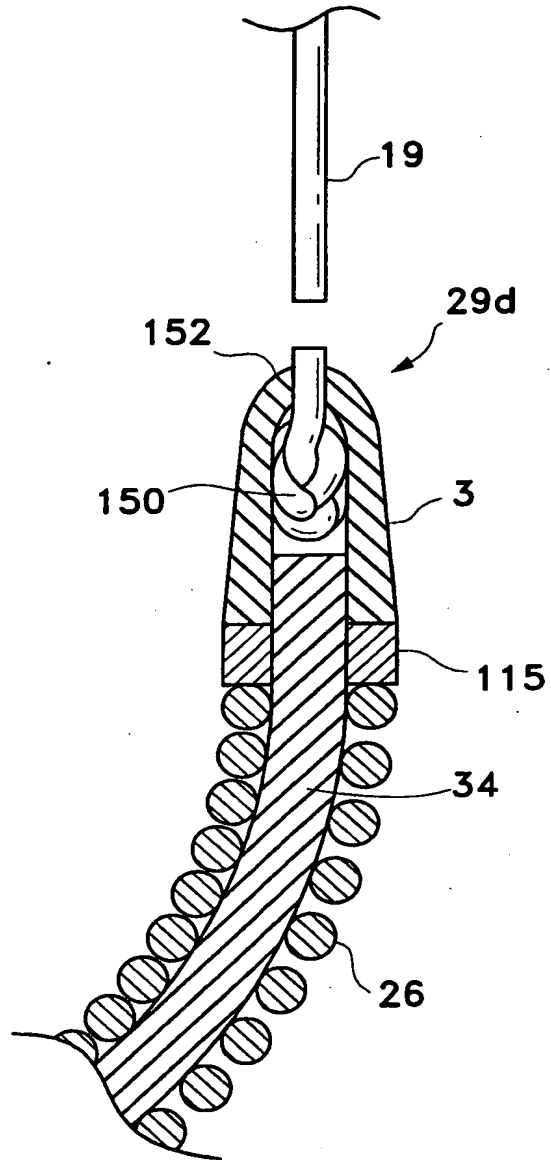


Fig. 15B

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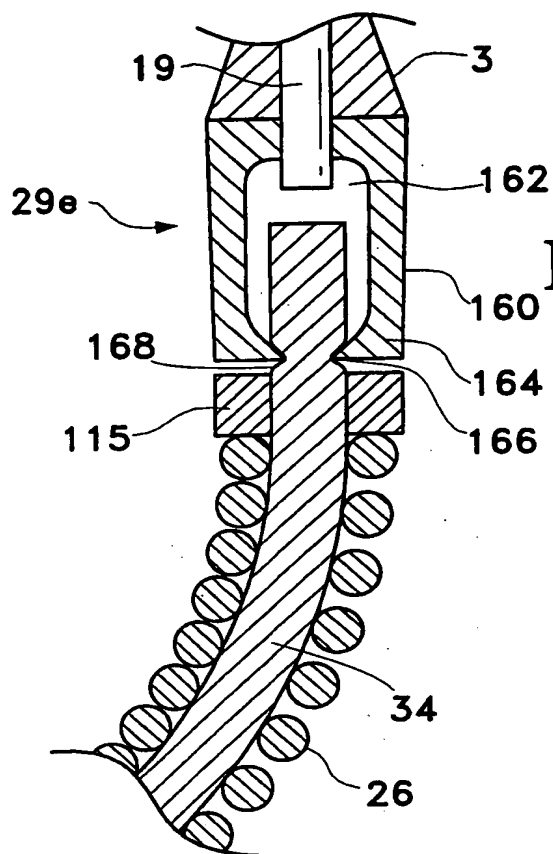
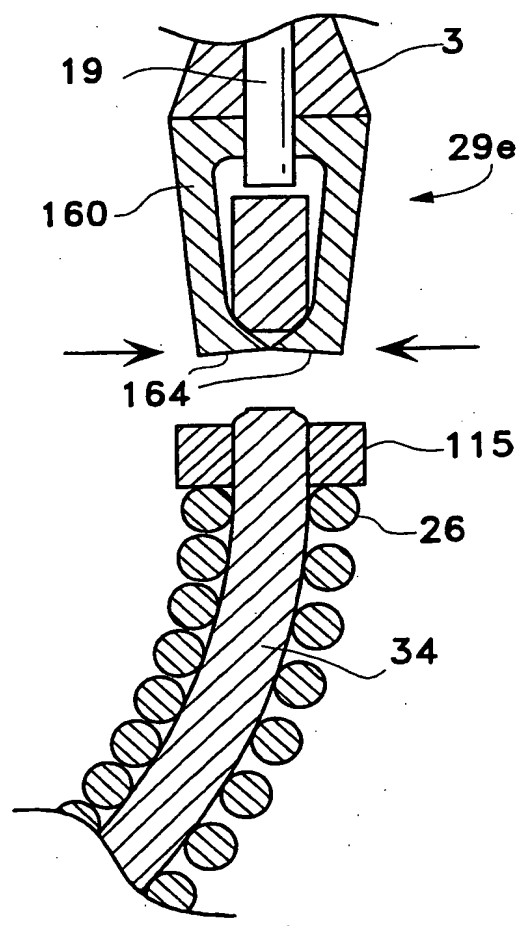


Fig. 16A

Fig. 16B



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Fig. 17A

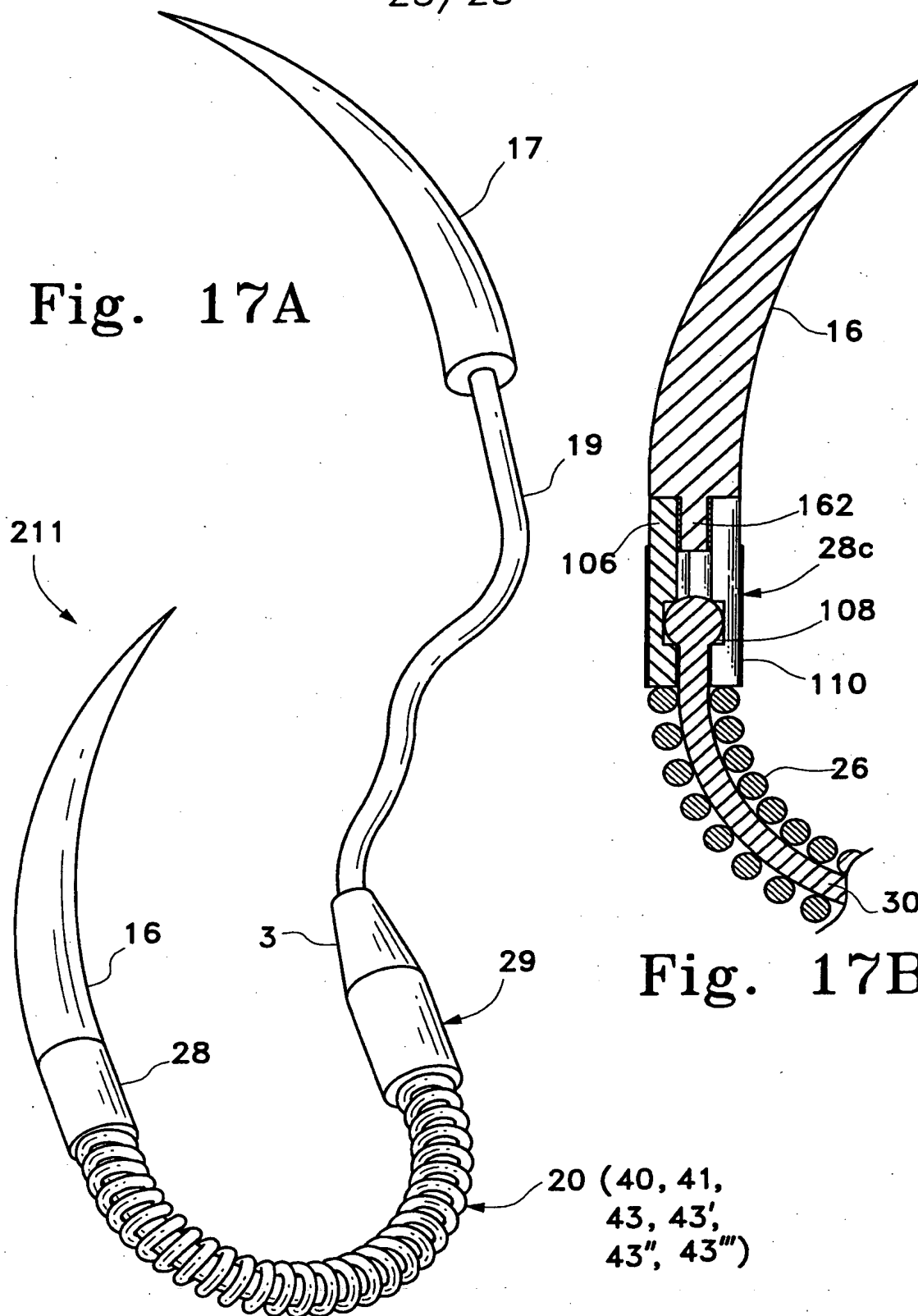
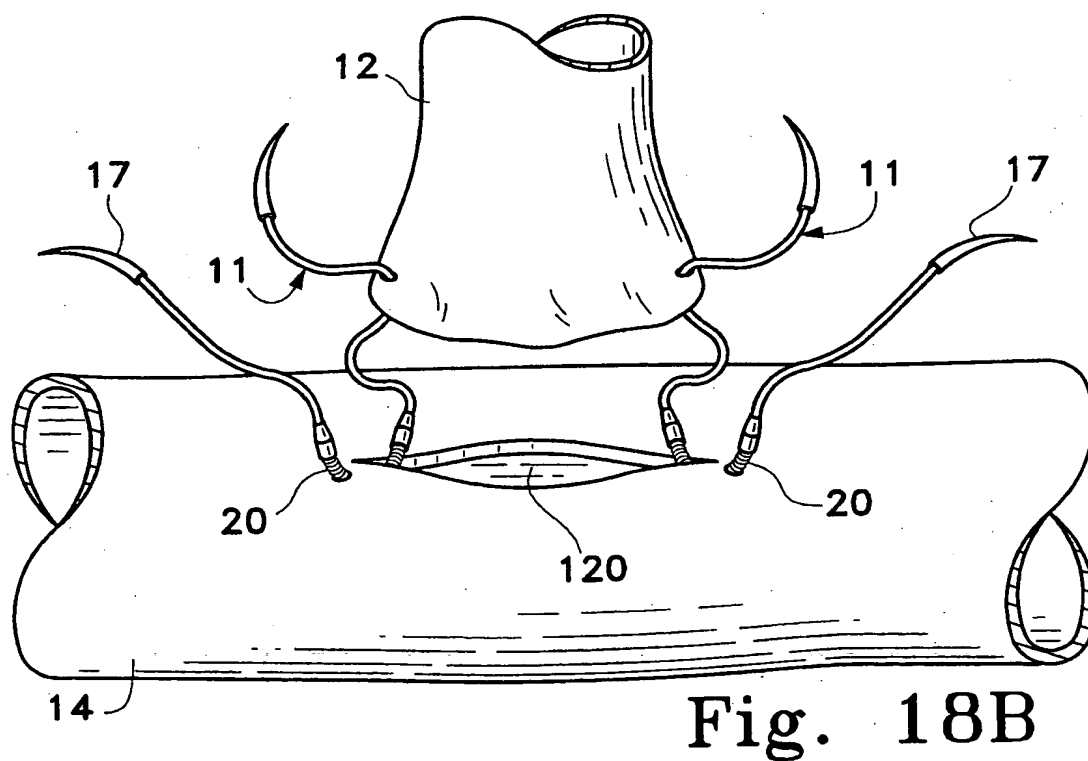
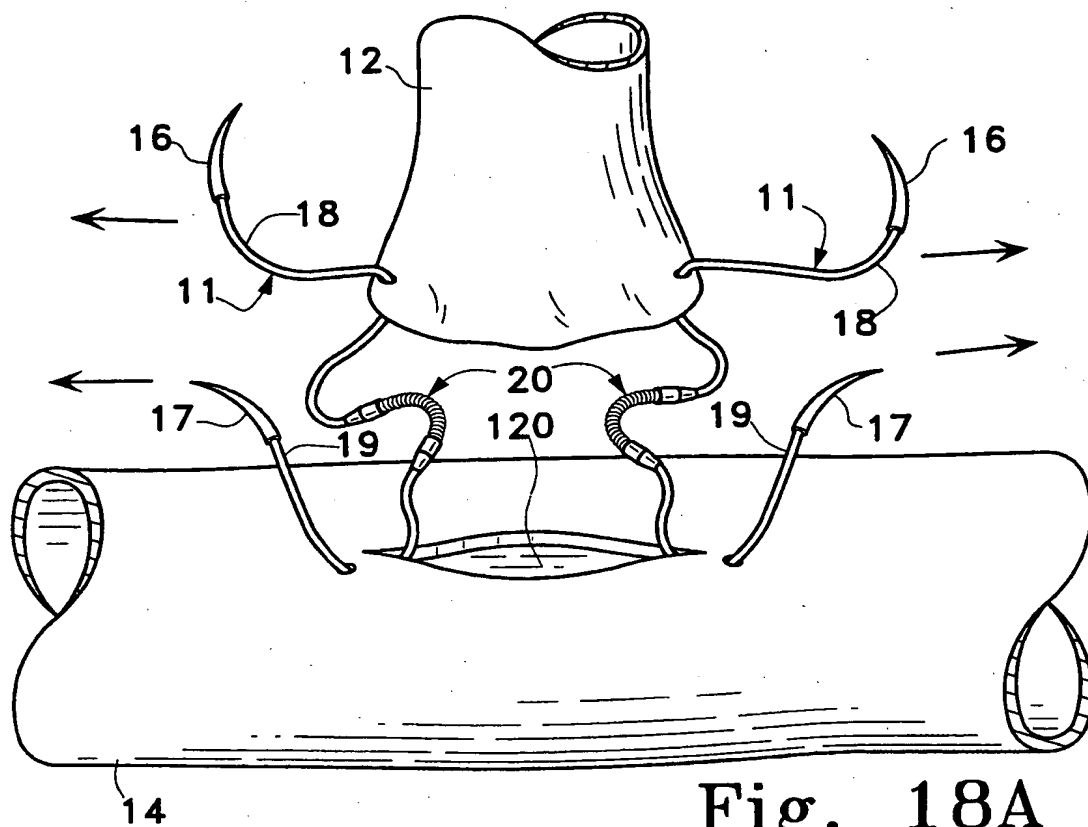


Fig. 17B

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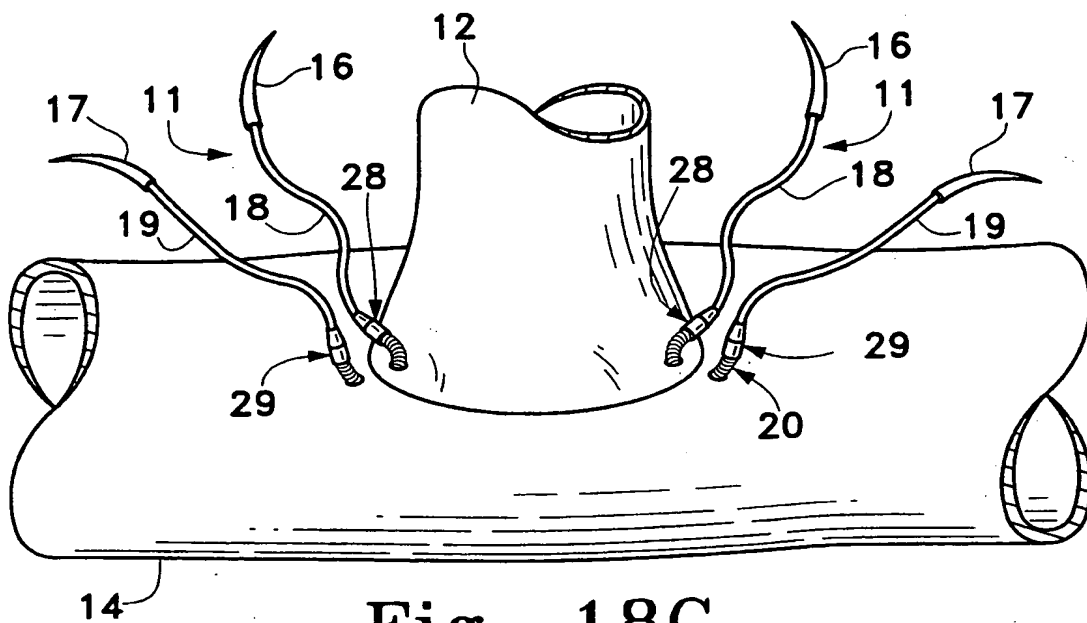


Fig. 18C

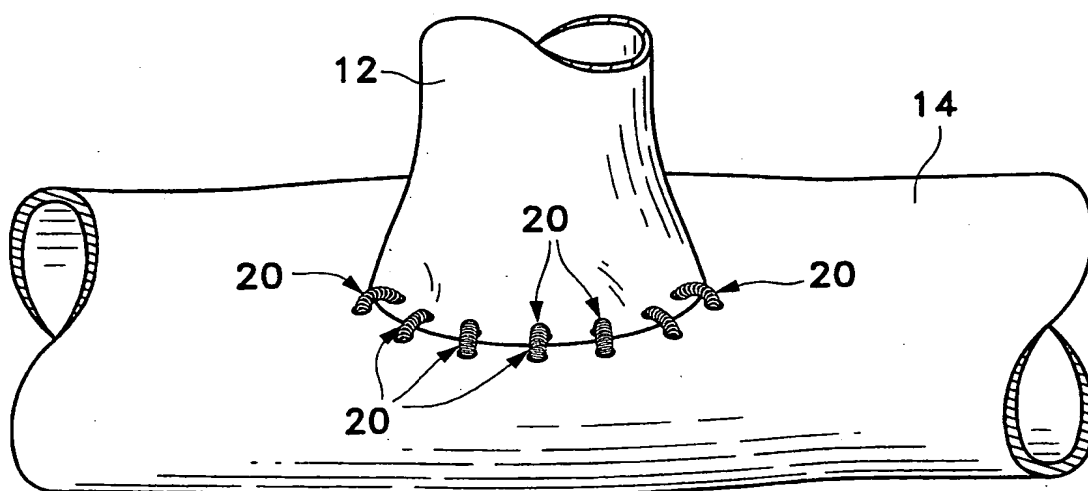


Fig. 18D

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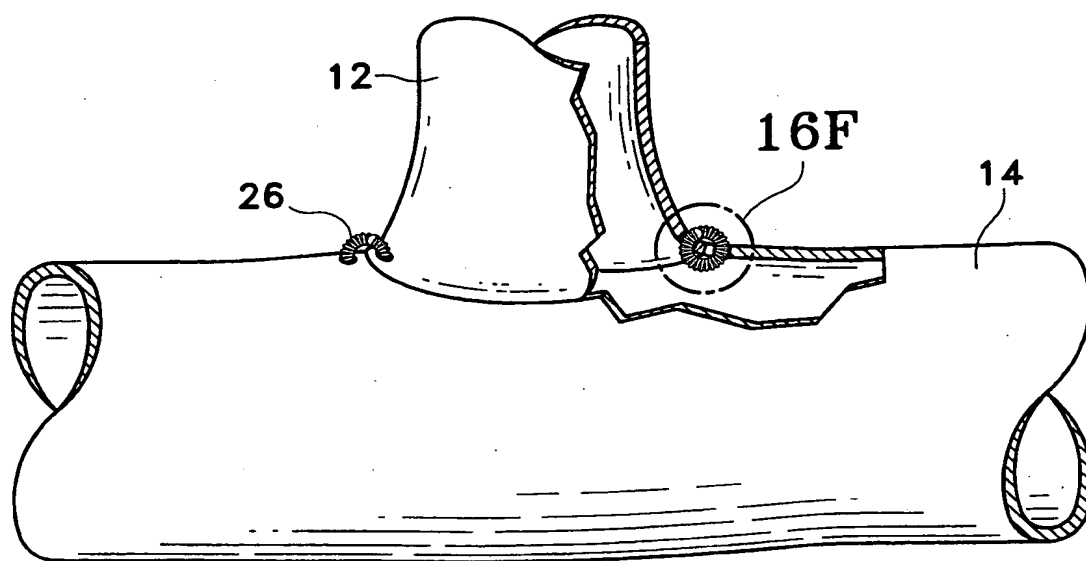


Fig. 18E